IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

BioNTech SE, BioNTech Manufacturing GmbH, and Pfizer Inc.,

Plaintiffs and Counter Defendants,

v.

CureVac SE (*f/k/a* CureVac AG),

Defendant and Counter Claimant,

and

CureVac Manufacturing GmbH,

Counter Claimant.

Civil Action No. 2:23-cv-0222 (JKW-DEM)

JURY TRIAL DEMANDED

BIONTECH AND PFIZER'S AMENDED COUNTERCLAIMS AND ANSWER TO CUREVAC'S FIRST AMENDED COUNTERCLAIMS

COUNTERCLAIMS

Pursuant to this Court's Order (D.I. 109), without admitting any of the allegations of CureVac SE and CureVac Manufacturing GmbH (collectively, "CureVac" or "Defendants") other than those expressly admitted herein, and without prejudice to the right of BioNTech SE and BioNTech Manufacturing GmbH (collectively, "BioNTech") and Pfizer Inc. ("Pfizer" and, together with BioNTech, "Plaintiffs") to plead additional counterclaims as the facts of the matter warrant, BioNTech and Pfizer assert the following counterclaims against CureVac.

INTRODUCTION

1. This action involves Plaintiffs' and Defendants' respective independent efforts to develop vaccines to combat the COVID-19 pandemic. Plaintiffs' Comirnaty® was the world's first mRNA vaccine approved for public use, deployed in record time, and proved to be effective in preventing severe disease, hospitalization, and death from the COVID-19 pandemic. BioNTech

worked tirelessly to create the mRNA vaccine after years of research and development of mRNA technology, collaborating with Pfizer to bring the vaccine through regulatory approval and distribution to combat this global pandemic. All of the investment and work paid off—BioNTech and Pfizer successfully developed an mRNA vaccine, proved its efficacy, established global manufacturing and supply chains, and gained regulatory approval. Their efforts played a vital role in managing the global COVID-19 crisis.

2. CureVac also tried to develop a vaccine to help the fight against COVID-19. Unlike BioNTech and Pfizer, CureVac was unsuccessful. Presumably using its alleged patented technology, CureVac's vaccine was an unsuccessful treatment and lacked sufficient efficacy for regulatory approval.

3. Failing to supply a useful vaccine, CureVac now attempts to profit from BioNTech and Pfizer's success through allegations of patent infringement. BioNTech and Pfizer, however, developed their Comirnaty® vaccine without any contribution from CureVac's alleged mRNA technology—which is why BioNTech and Pfizer brought this declaratory judgment action—instead relying on innovations from their own scientists and coordination with the global scientific community. CureVac played no part in Comirnaty®'s stunning success.

COMIRNATY® WAS BUILT ON DECADES OF PLAINTIFFS' AND THEIR PARTNERS' FOUNDATIONAL RESEARCH—NOT CUREVAC'S

4. Comirnaty® was the first-approved vaccine utilizing messenger RNA ("mRNA") technology. If efficacious, an mRNA vaccine works by introducing into a person mRNA that instructs the body to make a certain protein, such as a piece of a virus that the vaccine seeks to protect against. When that protein is made, or "expressed," by a person's cells, that person's immune system can recognize the protein as foreign and develop an immune response to it. If that person is later infected with the actual virus itself, his or her immune system is ready to protect

against or minimize the severity of the viral infection. This is unlike previously approved non-mRNA vaccines, developed before the COVID-19 pandemic, such as weakened or inactivated viruses injected into the patient.

5. Scientists have known since the 1970s that mRNA has the potential to be administered as a therapeutic to translate a protein that may treat or prevent disease in humans. By the 1990s, researchers demonstrated that mRNA administered as a therapeutic could be used to elicit antiviral immune responses in animal models, *e.g.*, encoding proteins expressed by cancer cells to induce an immune response.

6. One vexing problem encountered by researchers, however, was that synthetic mRNA can trigger proteins that result in a non-antigen-specific immune response, such as activation of toll-like receptors. This can lead to an undesirable reaction in the body, such as inflammation. Despite this, Dr. Katalin Karikó (a BioNTech scientist and professor at the University of Pennsylvania), was convinced that mRNA structures could be used to instruct cells to make their own therapeutic proteins.[1]

7. In the mid-2000s, after years of painstaking research, Dr. Karikó and Dr. Drew Weissman made a key breakthrough while they were both at the University of Pennsylvania: they discovered that certain chemical modifications to RNA nucleosides could reduce or eliminate the inflammatory reaction. They showed that the unmodified mRNA that they expressed induced an

[1] As Dr. Anthony Fauci acknowledged, Dr. Karikó "was, in a positive sense, kind of obsessed with the concept of messenger RNA." (D.I. 104, Ex. 1 at 1.) Despite her tenacity, Dr. Karikó struggled to stay afloat in academia, as she sought—and was denied—grant after grant to pursue ideas that seemed wild and fanciful to many in the academic community. (*Id.* at 1-2.) As one of her colleagues explained, "[w]hen your idea is against the conventional wisdom that makes sense to the star chamber, it is very hard to break out." (*Id.* at 1.) Yet, Dr. Karikó's focus and drive never wavered. Her genius was a "willingness to accept failure and keep trying, and her ability to answer questions people were not smart enough to ask." (*Id.* at 3.)

immune response, while the control—called transfer RNA ("tRNA"), an intermediary molecule used during protein translation that links the mRNA and the amino acid sequence of proteins—did not. In particular, they discovered that a class of nucleotides called pseudouridines found in tRNA allowed it to evade the cell's internal immune response.

8. This led Drs. Karikó and Weissman to investigate the idea of modifying uridines in mRNA with naturally occurring pseudouridines found in tRNA, including 1-methylpseudouridine. They discovered that the uridine modification helped synthetic mRNA evade the body's innate immune system. Drs. Karikó and Weissman published their insights in a series of research papers, including a seminal 2005 paper titled "Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA." (D.I. 104, Ex. 2.)[2]

9. Drs. Karikó and Weissman presented their ideas to pharmaceutical companies and venture capitalists. At first, no one was interested. As Dr. Weissman later recounted, "[w]e were screaming a lot, but no one would listen." (D.I. 104, Ex. 1 at 4.) BioNTech, however, took notice of Drs. Karikó and Weissman's work and began funding Dr. Karikó's laboratory. (*Id.*) In 2013, Dr. Karikó joined BioNTech full-time as a senior vice president.

10. Drs. Karikó and Weissman's discovery that modified mRNA nucleosides could evade the cell's internal immune response was the critical innovation behind the only fully

[2] Drs. Karikó and Weissman patented their groundbreaking discovery by submitting, in 2005, Provisional Patent Application No. 60/710,164 titled "RNA Containing Modified Nucleosides and Methods of Use Thereof." (D.I. 104, Ex. 3.) The '164 application describes how "[t]his invention provides RNA . . . comprising pseudouridine or a modified nucleoside" and expressly identifies N1-methyl-pseudouridine. (D.I. 104, Ex. 3 at 1, 14.) The '164 application further "provides methods of reducing the immunogenicity of RNA" by using mRNA with pseudouridine nucleotides. (*Id.* at 1.) The U.S. Patent Office eventually granted U.S. Patent No. 8,691,966 ("the '966 patent") to Drs. Karikó and Weissman, which claims priority to the '164 application. (D.I. 104, Ex. 4.) The '966 patent expressly claims mRNA comprising "a modified nucleoside selected from the group consisting of (i) 1-methypseudouridine ($m^1\Psi$) and (ii) pseudouridine (Ψ)." (D.I. 104, Ex. 4 at claim 1.)

approved mRNA COVID-19 vaccines, BioNTech and Pfizer's Comirnaty® and Moderna's Spikevax®. Moderna's co-founder, Derrick Rossi, recognized this discovery as "fundamental to this entire field" of mRNA vaccines and therapeutics. (D.I. 104, Ex. 5 at 2.) In Dr. Rossi's estimation, Drs. Karikó and Weissman's work will "earn them a Nobel Prize because it really is what allows these mRNA vaccines and any mRNA therapeutic down the road" (*id.*), and Moderna's co-founder reiterated that, "[i]f anyone asks [him] whom to vote for some day down the line, [he] would put them front and center" (D.I. 104, Ex. 6 at 7). According to Dr. Rossi, Drs. Karikó and Weissman's "fundamental discovery is going to go into medicines that help the world." (*Id.*) In fact, Moderna backed up Dr. Rossi's belief with its pocketbook by taking a license from the University of Pennsylvania's successor-in-interest, Cellscript, LLC so it could practice patents embodying Drs. Karikó and Weissman's "fundamental discovery," including patents disclosing the modified uridine that Moderna's mRNA vaccine uses. (*Id.*; D.I. 104, Ex. 7.)

11. For their discovery, Drs. Karikó and Weissman have been honored on several occasions by institutions such as the Columbia University Irving Medical Center and the European Patent Office for their "trailblazing" work, which "laid the foundation for the creation of [an] incredibly effective COVID-19 vaccine[.]" (Exs. 8, 9; *see also* Exs. 10 and 11.) Drs. Karikó and Weissman have also been presented with many other awards, such as the Princess of Asturias Award, the Albany Medical Center Prize in Medicine and Biomedical Research, the 2022 Breakthrough Prize in Life Sciences, and the 2021 Lasker Award—America's top biomedical research prize. (D.I. 104, Exs. 10, 12, 13, 14, 15, and 16.)

12. Dr. Karikó's continued research on modified mRNA at BioNTech included determining that an mRNA vaccine could elicit antibodies against the Zika virus. In 2017, Dr. Karikó co-authored a paper in *Nature* (the "2017 *Nature* Paper") demonstrating that "a single low-

dose intradermal immunization with lipid-nanoparticle-encapsulated nucleoside modified mRNA (mRNA-LNP) encoding the pre-membrane and envelope glycoproteins of a strain from the Zika Outbreak in 2013 elicited potent and durable neutralizing antibody responses" in animal models. (D.I. 104, Ex. 17 at 1.) The mRNA vaccine developed by BioNTech and the University of Pennsylvania against the Zika virus used mRNA that contained the modified nucleoside 1-methylpseudouridine, which is the same modified nucleoside that would later be used in Comirnaty®. (*Id.* at 2–3.)

13. BioNTech's development work included additional discoveries as part of its mRNA platform. For example, by 2014, scientists at BioNTech created the disrupted poly(A) tail that would later be used in Comirnaty®. (*See, e.g.*, D.I. 104, Ex. 18.) BioNTech's development work also involved collaborations with various partners. For example, by 2017, Acuitas Therapeutics, Inc. ("Acuitas") and BioNTech were collaborating on the development of mRNA therapeutic products using Acuitas' technology as a delivery system. During this time, Acuitas painstakingly engineered a microscopic sphere of fats called a lipid nanoparticle ("LNP") that can envelop and protect the mRNA. These LNPs allow the mRNA to cross the membrane of a human cell and then release the mRNA payload so it can be used to create the proteins that can potentially generate a protective immune response. BioNTech licensed LNPs from Acuitas for use with mRNA therapeutic products.

14. BioNTech's scientists, including Dr. Karikó, demonstrated that modified mRNA vaccines successfully conferred immunity against HIV, Zika, and influenza viruses in animal models; and published these results in the *Journal of Experimental Medicine* (the "2018 JEM Paper"). (*See* D.I. 105, Ex. 19.) The 2018 JEM Paper recognized that BioNTech's mRNA vaccine

platform has the "advantages of a favorable safety profile, potentially inexpensive manufacturing, and the *capacity for rapid development in emerging epidemics*." (*Id.* at 1580 (emphasis added).)

15. That same year, Pfizer and BioNTech partnered to develop an mRNA-based vaccine for influenza. As part of the agreement, BioNTech and Pfizer would jointly conduct research and development to advance mRNA-based flu vaccines. In announcing the collaboration, the head of Pfizer's vaccine research and development unit, Dr. Kathrin Jansen, noted that "[i]nnovative vaccine approaches are urgently needed to provide improved protection against seasonal flu, and to *respond rapidly and in quantity to pandemic influenza threats*." (D.I. 105, Ex. 20 at 1 (emphasis added).) Dr. Jansen further emphasized that "mRNA vaccines offer a novel approach to code for any protein or multiple proteins, and the potential to manufacture higher potency flu vaccines more rapidly and at a lower cost than contemporary flu vaccines." (*Id.*)

16. In December 2019, SARS-CoV-2 was reported in Wuhan, China. When this novel coronavirus emerged, BioNTech was well-positioned to respond rapidly by constructing a vaccine around its existing modified mRNA platform, which had already been tested against viruses such as HIV, Zika, and influenza. Leveraging decades of foundational research, BioNTech rapidly identified several candidates for clinical testing as mRNA-based vaccines to protect against COVID-19.

17. By early 2020, soon after the genetic sequence for SARS-CoV-2 (the virus that causes COVID-19) was published, BioNTech and its development partner Pfizer initiated "Project Lightspeed," an accelerated vaccine development program to fight COVID-19. BioNTech and Pfizer's COVID-19 vaccine development program leveraged BioNTech's experience and expertise with mRNA technologies, as well as the work of other partners, including Acuitas and the National Institutes of Health ("NIH").

18. For example, BioNTech developed innovative, proprietary mRNA-based technologies to achieve effective translational performance and direction of the immune response. BioNTech also leveraged its prior work with Acuitas on LNP technology and used Acuitas lipids ALC-315 and ALC-159. Further, BioNTech licensed and incorporated the work of NIH scientists relating to a particular modification to the sequence of the coronavirus spike protein (*i.e.*, the protein structures covering the exterior of the SARS-CoV-2 virus), which causes the modified spike protein to be locked in a certain configuration. (*See, e.g.*, D.I. 105, Ex. 21.) This configuration allows the modified spike protein to be recognized more easily by human cells and elicit a more robust bodily response that results in immunity.

19. With the benefit of its prior development work for its mRNA platform, BioNTech rapidly developed and performed numerous toxicological and pharmacological studies to determine the safety and efficacy of the Comirnaty® vaccine. For example, BioNTech's studies showed, *inter alia*, that the vaccine is highly immunogenic in animal models and provided the confirmation needed to move quickly into Phase 1 clinical studies.

20. BioNTech partnered with Pfizer on the development, clinical testing, manufacturing, distribution, and regulatory approval of the Comirnaty® vaccine. (*See* D.I. 1, Exhibit 6.) By March 2020, when the World Health Organization ("WHO") declared the COVID-19 outbreak a global pandemic, Pfizer and BioNTech had already begun their collaborative effort.

21. Clinical trials of the Comirnaty® vaccine began in late April 2020, with preliminary results demonstrating its safety and efficacy published within six months. This rapid development and start of clinical trials of product candidates was not a chance event, the result of sudden inspiration, or copying someone else's work. It was the result of the relentless work by dedicated scientists and the vision of BioNTech and Pfizer working together.

22. On May 5, 2020, BioNTech and Pfizer announced that the first participants had been dosed in the United States in the Phase 1/2 clinical trial for their vaccine, codenamed BNT162, designed to determine safety and efficacy against COVID-19. (*See* D.I. 1, Exhibit 9.) After attaining promising Phase 1/2 clinical study results, on July 27, 2020, BioNTech and Pfizer began a Phase 2/3 study on their Comirnaty® vaccine. (*See* D.I. 1, Exhibit 12.) The pivotal Phase 3 study was conducted on a global scale—encompassing more than 44,000 patients—to continue determining its safety and efficacy in humans. (*See* D.I. 1, Exhibit 8.)

23. Meanwhile, Pfizer was also working on the logistics and infrastructure needed to successfully manufacture and distribute the Comirnaty® vaccine. Pfizer leveraged its extensive manufacturing network to produce an approved COVID-19 vaccine as quickly as possible for those most in need in the United States.

24. In November 2020, the Comirnaty® vaccine was shown to have met all the primary efficacy endpoints in a Phase 3 clinical trial, demonstrating an "efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and in participants with and without prior SARS-CoV-2 infection (second primary objective)," as measured from seven days after the second dose of the vaccine. (*See* D.I. 1, Exhibit 13.)

25. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted the clinical trial data as part of an Emergency Use Authorization ("EUA") request to the Food and Drug Administration ("FDA") for administering the Comirnaty® vaccine to people 16 years of age and older.

26. On December 11, 2020, the FDA granted the first EUA for a COVID-19 vaccine to Pfizer and BioNTech's Comirnaty® vaccine with vaccinations rolling out immediately thereafter,[3] completing the fastest development of a vaccine in history.

27. Based on a comprehensive data package and real-world results demonstrating overwhelming safety and efficacy, on August 23, 2021, the FDA granted full approval of the Comirnaty® vaccine for individuals 16 years of age and older. In late 2021 and early 2022, the FDA amended its emergency use authorization for Comirnaty® to permit administration of a booster dose in certain individuals after completing their primary two-dose series with an FDA-authorized or approved COVID-19 vaccine, including Comirnaty®. The Comirnaty® vaccine was both the first mRNA drug product and the first COVID-19 vaccine to receive full FDA approval. BioNTech Manufacturing GmbH is the Biologics License Application holder for Comirnaty® in the United States.

28. Since receiving the first EUA from the FDA, Comirnaty® vaccine has contributed to saving at least 14 million lives that otherwise may have been lost due to the pandemic. (*See* D.I. 1, Exhibit 16.) Furthermore, widespread vaccination of populations with Comirnaty® vaccine allowed jurisdictions worldwide, including Virginia, to remove restrictions on movement, easing the economic and social burdens countless individuals suffered during forced isolation.

[3] FDA Memorandum, Emergency Use Authorization ("EUA") for an Unapproved Product Review (Dec. 11, 2020), https://www.fda.gov/media/144416/download; Press Release, FDA, FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/newsevents/pressannouncements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-useauthorization-first-covid-19.

CUREVAC NOW SEEKS TO PROFIT FROM PFIZER AND BIONTECH'S VACCINE AFTER ITS OWN VACCINE FAILED

29. Like BioNTech and Pfizer, CureVac also tried to develop a vaccine containing mRNA packaged in an LNP to fight the COVID-19 pandemic. Unlike BioNTech and Pfizer, however, CureVac failed to create an mRNA vaccine against COVID-19 that induced a sufficient protective immune response.

30. Upon information and belief, on or about June 16, 2021, a pivotal Phase 2b/3 clinical trial showed that CureVac's COVID-19 vaccine candidate, "CVnCoV," had an interim vaccine efficacy of about 47% against COVID-19 of any severity, which did not meet the pre-specified statistical success criteria. (*See* D.I. 1, Exhibit 4.)

31. Upon information and belief, an earlier Phase 1 study of CVnCoV showed that serum levels of so-called neutralizing antibodies, which prevent the virus from binding to cells, were relatively low in vaccine recipients compared with people who were naturally infected with SARS-CoV-2.

32. Upon information and belief, after failing to develop its own effective COVID-19 vaccine, CureVac set its sights on profiting off BioNTech and Pfizer's Comirnaty® vaccine through baseless allegations of patent infringement. In its Counterclaims, CureVac improperly attempts to inflate its scientific contributions to the field of mRNA therapeutics. For example, CureVac alleges that its "discoveries span all aspects of mRNA medicines, including methods to stabilize mRNA, to modify it, to manufacture it on a commercial scale, to increase the yield of the protein it encodes, and to formulate it for safe and effective administration to patients." (D.I. 106 at ¶ 4.) Despite all of these "discoveries," and CureVac's allegation that it "was the first company in the world to harness mRNA for medical purposes" (D.I. 106 at ¶ 3), when the global community called for a COVID-19 vaccine, CureVac was unable to provide one.

33. CureVac also alleges that, "[w]hen the COVID-19 pandemic struck, CureVac scientists leveraged their resources and expertise to find the optimal mRNA sequence encoding the full-length COVID-19 spike protein and packaged that mRNA in the LNP that resulted from CureVac's selection and validation process in the human rabies vaccine trial." (D.I. 106 at ¶ 26.) CureVac did not discover the sequence of the SARS-CoV-2 spike protein, despite citing it in U.S. Patent Nos. 11,241,493 ("the '493 patent"), 11,471,525 ("the '525 patent"), 11,576,966 ("the '966 patent"), and 11,596,686 ("the '686 patent"); that information was publicly available before February 2020. (*See*, *e.g.*, D.I. 105, Exs. 22 and 23.) Likewise, CureVac did not discover the basic idea of an mRNA vaccine to elicit an immune response against a specific viral antigen or the particular modification to the sequence of a coronavirus spike protein that stabilizes the spike protein, which allows it to be used effectively as an mRNA vaccine antigen. Instead, NIH scientists described the specific spike protein sequence modification. (*See, e.g.*, D.I. 105, Ex. 21.)

34. CureVac also did not create the LNP in which the mRNA is packaged because that was done by Acuitas and disclosed publicly prior to the filing of CureVac's patents in suit. (*See, e.g.*, D.I. 105, Exs. 24-26.)

35. CureVac also alleges that it "discovered that increasing the proportions of guanosine and cytidine nucleosides in an mRNA stabilizes the molecule and results in an increased expression of the protein it encodes." (D.I. 106 at ¶ 19.) This is incorrect. U.S. Patent No. 11,135,312 ("the '312 patent") does not disclose the stabilization of any mRNA or increased expression of any protein. Regardless, codon optimization of viral nucleic acid coding sequences for increasing expression in mammalian cells over the wild type virus was known years before CureVac's patent applications were filed. (*See, e.g.*, D.I. 105, Exs. 27-29.)

36. CureVac's broad allegations demonstrate that CureVac is not attempting to protect a specific composition, but rather seeks to preempt others from using prior art methods that were known and practiced by scientists before CureVac's applications were filed. (D.I. 106 at ¶ 19.) CureVac should not be permitted to monopolize an entire class of alleged inventions by claiming them according to their function (*e.g.*, the stabilization of any mRNA or enhanced expression of any protein), especially where its patent specification does not even show that claimed function.

37. CureVac further asserts that it "discovered that modifying one of [mRNA's] untranslated regions, composed of sequential adenosine nucleotides at one end of the mRNA (often called 'polyA'), results in a substantial increase in the amount of protein expressed by the cell or organism." (D.I. 106 at ¶ 21.) But again, this concept of modifying mRNA using "polyA," as CureVac attempts to claim in U.S. Patent Nos. 11,149,278 ("the '278 patent"), 11,286,492 ("the '492 patent"), and 11,345,920 ("the '920 patent") (*see* D.I. 106 at ¶ 21), is broad and was previously known in the art (*see, e.g.* D.I. 104, Ex. 18; D.I. 105, Exs. 30 and 31). Also, upon information and belief, the U.S. Government has certain rights, including "have made" rights, in the asserted patents, including at least the '278, '492 and '920, patents.

38. CureVac also alleges that it "developed new methods to purify the mRNA, as well as the DNA template which encodes the mRNA, using a technique called Tangential Flow Filtration ('TFF')." (D.I. 106 at ¶ 23.) Once again, this is not true. The prior art reveals that the use of TFF was known to purify nucleic acids, including plasmid DNA and RNA, before the applications leading to U.S. Patent Nos. 10,760,070 ("the '070 patent") and 11,667,910 ("the '910 patent") were filed. (*See, e.g.*, D.I. 105, Exs. 32-36.) Also, upon information and belief, the U.S. Government has certain rights, including "have made" rights, in the asserted patents, including at least the '070 and '910 patents.

39. Upon information and belief, CureVac sought to broaden its patent portfolio beyond what it actually invented, in an effort to collect and leverage well known and fundamental research discoveries made by others for its own financial gain.

40. For these reasons, and as set forth more fully in these Counterclaims and Answer to Counterclaims, BioNTech and Pfizer deny CureVac's allegations, deny that CureVac is entitled to any relief, and seek the relief described below.

PARTIES

41. BioNTech SE is a company organized and existing under the laws of Germany, having a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

42. BioNTech Manufacturing is a company organized and existing under the laws of Germany, having a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

43. BioNTech Manufacturing is a wholly owned subsidiary of BioNTech SE.

44. Pfizer is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 66 Hudson Blvd E, New York, NY 10001-2192, USA.

45. Upon information and belief, CureVac SE is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany.

46. Upon information and belief, CureVac Manufacturing GmbH is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany. CureVac Manufacturing GmbH is a wholly-owned subsidiary of CureVac N.V.

JURISDICTION AND VENUE

47. BioNTech and Pfizer seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202. The Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

48. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by CureVac's choice of forum.

49. This action is based upon an actual controversy between the parties arising from allegations of infringement of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents.

COUNT I - DECLARATION OF INVALIDITY OF THE '312 PATENT

50. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

51. As set forth above, and in particular, in paragraphs 32, 35-36, and 39, the claims of the '312 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

52. Without limitation, the claims of the '312 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraph 35.

53. In addition, the claims of the '312 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT II - DECLARATION OF INVALIDITY OF THE '278 PATENT

54. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

55. As set forth above, and in particular, in paragraphs 32, 37 and 39, the claims of the '278 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

56. Without limitation, the claims of the '278 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraph 37.

57. In addition, the claims of the '278 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT III - DECLARATION OF INVALIDITY OF THE '492 PATENT

58. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

59. As set forth above, and in particular, in paragraphs 32, 37 and 39, the claims of the '492 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

60. Without limitation, the claims of the '492 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraph 37.

61. In addition, the claims of the '492 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT IV - DECLARATION OF INVALIDITY OF THE '920 PATENT

62. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

63. As set forth above, and in particular, in paragraphs 32, 37 and 39, the claims of the '920 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

64. Without limitation, the claims of the '920 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraph 37.

65. In addition, the claims of the '920 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT V - DECLARATION OF INVALIDITY OF THE '070 PATENT

66. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

67. As set forth above, and in particular, in paragraphs 32, 38 and 39, the claims of the '070 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

68. Without limitation, the claims of the '070 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraph 38.

69. In addition, the claims of the '070 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT VI - DECLARATION OF INVALIDITY OF THE '910 PATENT

70. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

71. As set forth above, and in particular, in paragraphs 32, 38 and 39, the claims of the '910 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

72. Without limitation, the claims of the '910 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraph 38.

73. In addition, the claims of the '910 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT VII - DECLARATION OF INVALIDITY OF THE '493 PATENT

74. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

75. As set forth above, and in particular, in paragraphs 32, 33, 34, and 39, the claims of the '493 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

76. Without limitation, the claims of the '493 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraphs 33 and 34.

77. In addition, the claims of the '493 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT VIII - DECLARATION OF INVALIDITY OF THE '525 PATENT

78. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

79. As set forth above, and in particular, in paragraphs 32, 33, 34, and 39, the claims of the '525 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

80. Without limitation, the claims of the '525 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraphs 33 and 34.

81. In addition, the claims of the '525 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT IX - DECLARATION OF INVALIDITY OF THE '966 PATENT

82. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

83. As set forth above, and in particular, in paragraphs 32, 33, 34, and 39, the claims of the '966 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability

of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

84. Without limitation, the claims of the '966 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraphs 33 and 34.

85. In addition, the claims of the '966 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT X - DECLARATION OF INVALIDITY OF THE '686 PATENT

86. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

87. As set forth above, and in particular, in paragraphs 32, 33, 34, and 39, the claims of the '686 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

88. Without limitation, the claims of the '686 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in paragraphs 33 and 34.

89. In addition, the claims of the '686 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

COUNT XI - DECLARATION OF NONINFRINGEMENT OF THE '492 PATENT

90. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

91. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '492 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '492 patent.

92. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '492 patent.

COUNT XII - DECLARATION OF NONINFRINGEMENT OF THE '920 PATENT

93. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

94. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '920 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '920 patent.

95. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '920 patent.

COUNT XIII - DECLARATION OF NONINFRINGEMENT OF THE '070 PATENT

96. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

97. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '070 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '070 patent.

98. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '070 patent.

COUNT XIV - DECLARATION OF NONINFRINGEMENT OF THE '910 PATENT

99. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

100. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '910 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '910 patent.

Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '910 patent.

COUNT XV - DECLARATION OF NONINFRINGEMENT OF THE '525 PATENT

101. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

102. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '525 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '525 patent.

103. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '525 patent.

COUNT XVI - DECLARATION OF NONINFRINGEMENT OF THE '966 PATENT

104. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

105. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '966 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '966 patent.

106. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '966 patent.

COUNT XVII - DECLARATION OF NONINFRINGEMENT OF THE '686 PATENT

107. Pfizer and BioNTech reallege and incorporate by reference paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

108. CureVac has accused BioNTech and Pfizer of activities that it claims infringe the '686 patent. BioNTech and Pfizer deny that they have infringed any valid and/or enforceable claim of the '686 patent.

109. Pfizer and BioNTech are entitled to a judicial determination that they have not infringed and will not infringe, directly or indirectly, any valid claim of the '686 patent.

* * *

JURY DEMAND

110. Pursuant to Fed. R. Civ. Pro. 38, Plaintiffs request a trial by jury of any issue triable of right by a jury.

DEMAND FOR JUDGMENT

111. WHEREFORE, Counterclaim Plaintiffs Pfizer and BioNTech pray for the following relief in addition to the relief requested in their original Complaint (D.I. 1):

a) That the Court order CureVac's counterclaims be dismissed with prejudice and judgment be entered in favor of Pfizer and BioNTech;

b) That a judgment be entered declaring that Pfizer and BioNTech's conduct has not infringed and will not infringe, directly or indirectly, any valid and/or enforceable claim of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents;

c) That a judgment be entered declaring the claims of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents invalid;

d) That a judgment be entered declaring that the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents are unenforceable against Pfizer and BioNTech;

e) That CureVac and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Pfizer and BioNTech or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Pfizer and BioNTech, or charging any of them either orally or in writing with infringement of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents;

f) That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Pfizer and BioNTech are therefore entitled to recover their reasonable attorneys' fees upon prevailing in this action;

g) That Pfizer and BioNTech be awarded costs, attorney's fees, and other relief, both legal and equitable, to which they may be justly entitled; and

h) That Pfizer and BioNTech be awarded such other and further relief as is just and proper.

ANSWER TO FIRST AMENDED COUNTERCLAIMS

BioNTech and Pfizer respond to each of the allegations in the First Amended Counterclaims of CureVac (D.I. 106). Any allegations not expressly admitted are denied. This answer follows the numbering provided in CureVac's First Amended Counterclaims. To the extent that the section headings of CureVac's First Amended Counterclaims contain allegations, those allegations are denied. To the extent CureVac's footnotes contain allegations, those allegations are denied.

CUREVAC'S ALLEGED PIONEERING WORK ON mRNA MEDICINES

1. CureVac was the pioneer in the development of a completely new class of medicines based on messenger RNA (mRNA). These medicines use the mRNA molecule as a carrier of information to allow the body to produce its own active substances to treat or prevent disease. Although many doubted that this technology could ever be used to treat or prevent disease, CureVac recognized very early that it had great potential to improve patients' lives. Since CureVac's founding in 2000 in Tübingen, Germany, CureVac has been singularly focused on making mRNA medicines a reality through substantial investment and more than two decades of research and development.

ANSWER: BioNTech and Pfizer deny the first sentence. BioNTech and Pfizer admit that medicines based on mRNA, if successful, may "allow the body to produce its own active substances to treat or prevent disease." BioNTech and Pfizer deny the remaining allegations of Paragraph 1 on the basis that they are subjective and vague, and because BioNTech and Pfizer lack knowledge of what CureVac "recognized" and what was CureVac's "focus."

2. As a molecule found within all forms of cellular life, mRNA is central to biology: it is literally the "messenger" between DNA, the body's genetic blueprint, and proteins, the molecules responsible for the structure, function, and regulation of essentially all processes in the body. For many years after its discovery, mRNA was considered too unstable to be used therapeutically (mRNA is quickly destroyed both outside and inside the body), and was therefore relegated into the shadow of its much more stable sister molecule, DNA. But in the late 1990s, CureVac's founder, Dr. Ingmar Hoerr (although only a graduate student at the time), made a completely unexpected discovery: despite being unstable, mRNA could be directly administered to animals, without complicated reformulations or molecular packaging, where it could cause cells to produce the protein encoded by the mRNA.

ANSWER: BioNTech and Pfizer admit that mRNA is "a molecule found within all forms of cellular life," and is the "messenger" between DNA and the proteins. BioNTech and Pfizer are not aware of any "unexpected discovery" that CureVac has made in the field of mRNA technology. BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 and therefore deny them.

3. With this ground-breaking discovery, in 2000, Dr. Hoerr and others founded CureVac and began to challenge the status quo by developing this unproven technology to treat and prevent some of the deadliest diseases and medical conditions, including cancer. Despite other companies' current claims to be the "pioneers" in this field, CureVac was the first company in the world to harness mRNA for medical purposes—because the CureVac scientists saw opportunities where others saw only obstacles.

ANSWER: BioNTech and Pfizer are not aware of any "ground-breaking discovery" that CureVac has made in the field of mRNA technology. BioNTech and Pfizer deny that CureVac was "the first company in the world to harness mRNA for medical purposes." To the extent Paragraph 3 alleges that CureVac was the first to realize the potential of mRNA medicines for treating or preventing disease or improving patient lives—or that CureVac was the only company focused on mRNA technology—BioNTech and Pfizer deny those allegations. BioNTech and Pfizer deny the remaining allegations of Paragraph 3 on the basis that they are subjective and vague, and because BioNTech and Pfizer lack knowledge of what opportunities CureVac "saw."

4. Convinced that mRNA has unparalleled potential as a medicine, CureVac's scientists have worked diligently in its laboratories to pioneer numerous fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines, including methods to stabilize mRNA, to modify it, to manufacture it on a commercial scale, to increase the yield of the protein it encodes, and to formulate it for safe and effective administration to patients.

ANSWER: BioNTech and Pfizer are not aware of any "fundamental breakthroughs" that CureVac has made in the field of mRNA technology. BioNTech and Pfizer deny that CureVac pioneered discoveries that "span all aspects of mRNA medicines." To the extent Paragraph 4 alleges that CureVac was the first to formulate mRNA medicines for safe and effective

administration to patients to fight COVID-19, BioNTech and Pfizer deny those allegations. BioNTech and Pfizer deny the remaining allegations of Paragraph 4, including on the basis that they are subjective and vague.

5. Based on that research, CureVac is developing medicines to treat and prevent a wide range of diseases—infectious diseases like COVID-19 and influenza, liver and eye diseases, and particularly treatment-resistant cancers.

ANSWER: BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 5 and therefore deny them.

6. All told, CureVac and its 1000 employees invested many thousands of hours and more than a billion dollars to develop an mRNA medicines platform that could be applied across a variety of therapeutic and prophylactic (*e.g.*, vaccine) applications.

ANSWER: BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 6 and therefore deny them.

PARTIES

7. CureVac SE is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany. In September 2022, CureVac AG was merged with CureVac Beteiligungsverwaltungs AG (registered office in Vienna, Austria). As part of that merger, CureVac AG changed its name to CureVac SE, which on September 26, 2022, was registered in the Stuttgart commercial register.

ANSWER: BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 7 and therefore deny them.

8. CureVac Manufacturing GmbH is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany. CureVac Manufacturing GmbH is a wholly-owned subsidiary of CureVac N.V.

ANSWER: BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 8 and therefore deny them.

9. CureVac SE and CureVac Manufacturing GmbH are the owners by assignment of the patents asserted in this litigation.

ANSWER: BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 9 and therefore deny them.

10. On information and belief, Pfizer is a corporation organized and existing under the laws of Delaware, with its principal place of business at 235 East 42nd Street, New York, NY 10017.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 10.

11. On information and belief, BioNTech SE is a corporation organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

ANSWER: BioNTech and Pfizer admit the allegations of Paragraph 11.

12. On information and belief, BioNTech Manufacturing, a wholly-owned subsidiary of BioNTech SE, is a limited liability company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

ANSWER: BioNTech and Pfizer admit the allegations of Paragraph 12.

13. On information and belief, BioNTech Manufacturing is the Biologics License Application ("BLA") holder for Comirnaty® in the United States.

ANSWER: BioNTech and Pfizer admit the allegations of Paragraph 13.

14. On information and belief, Pfizer and BioNTech jointly developed and commercialized Comirnaty®.

ANSWER: BioNTech and Pfizer admit the allegations of Paragraph 14.

JURISDICTION AND VENUE

15. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201 and 2202.

ANSWER: The allegations of paragraph 15 purport to characterize CureVac's counterclaims, which speak for themselves, and set forth legal conclusions, to which no response is required. To the extent a response is required, BioNTech and Pfizer deny that they have infringed or will infringe, directly or indirectly, the patents-in-suit.

16. Personal jurisdiction is proper in this Court over Pfizer and BioNTech at least because, on information and belief, Pfizer and BioNTech engaged in infringing acts in this District.

ANSWER: The allegations of Paragraph 16 set forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 16 but do not contest personal jurisdiction in the Eastern District of Virginia for purposes of this case only.

17. Pfizer and BioNTech have consented to venue in this Court by filing their declaratory judgment complaint, which was transferred to this Court, and venue is proper pursuant to 28 U.S.C. §§ 1391(b)–(c).

ANSWER: The allegations of Paragraph 17 set forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 17 but do not contest that venue in the Eastern District of Virginia for purposes of this case only.

CUREVAC'S PATENTS

18. The use of mRNA as a vaccine has long been hampered by, for example, its instability, the difficulty in getting it inside the target cells in the body, its inability to produce sufficient quantities of the desired protein once it is inside those cells, the insufficient stimulation of the immune system by the expressed protein, and various undesirable side effects (called "reactogenicity"). In its more than two decades of developing mRNA technologies, CureVac encountered and developed solutions to these many technical challenges presented by this entirely new way to treat and prevent disease. CureVac has sought to protect its substantial investment in research and development in the field of mRNA medicines by obtaining patents that cover its inventions.

ANSWER: BioNTech and Pfizer admit the information in the first sentence of Paragraph 18 was known as early as 2000. BioNTech and Pfizer deny the remaining allegations in Paragraph 18.

19. To overcome the instability of mRNA so that it could be used in vaccines and other medicines, CureVac's scientists had to develop novel ways to stabilize it by modifying its structure. mRNA typically is composed of four different nucleosides: adenosine, guanosine, cytidine, and uridine. The sequence of these nucleosides in an mRNA molecule provides instructions that cells use to create the particular protein it encodes. CureVac's scientists

discovered that increasing the proportions of guanosine and cytidine nucleosides in an mRNA stabilizes the molecule and results in an increased expression of the protein it encodes. In 2001, CureVac filed its first patent application directed to this advance in mRNA technology.

ANSWER: BioNTech and Pfizer admit the information in the second and third sentences of paragraph 19 were known as early as 2000. BioNTech and Pfizer deny the remaining allegations in Paragraph 19.

20. On October 5, 2021, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,135,312 ("the '312 patent") titled "Pharmaceutical Composition Containing a Stabilised mRNA Optimised for Translation in its Coding Regions." The '312 patent names CureVac's co-founders, Florian Von der Mülbe, Ingmar Hoerr, and Steve Pascolo, as inventors. A true and correct copy of the '312 patent is attached as Exhibit 1.

ANSWER: BioNTech and Pfizer admit that the '312 patent, on its face, is titled "Pharmaceutical Composition Containing a Stabilised mRNA Optimised for Translation in its Coding Regions" and lists Florian Von der Mülbe, Ingmar Hoerr, and Steve Pascolo as inventors. BioNTech and Pfizer admit that Exhibit 1 is a document that purports to be a copy of the '312 patent. BioNTech and Pfizer deny any remaining allegations of Paragraph 20.

21. The levels at which an mRNA expresses the protein it encodes is of primary importance to the development of an mRNA vaccine. An mRNA has discrete parts: the part that is translated to make a protein inside a cell, and the other, untranslated, parts that facilitate the translation. CureVac scientists discovered that modifying one of those untranslated regions, composed of sequential adenosine nucleotides at one end of the mRNA (often called "polyA"), results in a substantial increase in the amount of protein expressed by the cell or organism. In 2014, CureVac filed its first patent application directed to this advance in mRNA technology. On October 19, 2021, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,149,278 ("the '278 patent") titled "Artificial nucleic acid molecules for improved protein expression." A true and correct copy of the '278 patent is attached as Exhibit 2. On March 29, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,286,492 ("the '492 patent") titled "Artificial nucleic acid molecules for improved protein expression." A true and correct copy of the '492 patent is attached as Exhibit 3. On May 31, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,345,920 ("the '920 patent") titled "Artificial nucleic acid molecules for improved protein expression." A true and correct copy of the '920 patent is attached as Exhibit 4. The '278, '492, and '920 patents list Andreas Thess, Thomas Schlake, and Stefanie Grund as inventors.

ANSWER: BioNTech and Pfizer admit that levels of protein expression are among the important factors for development of an mRNA vaccine, and that "mRNA" is a broad term that

includes a functional definition. BioNTech and Pfizer admit that the '278, '492, and '920 patents, on their face, are titled "Artificial nucleic acid molecules for improved protein expression" and list Andreas Thess, Thomas Schlake, and Stefanie Grund as inventors. BioNTech and Pfizer admit that Exhibits 2, 3, and 4 are documents that purport to be copies of the '278, '492, and '920 patents. BioNTech and Pfizer deny any remaining allegations of Paragraph 21.[4]

23. The development of mRNA into a viable alternative to traditional drug products required the development of a commercially viable, efficient, and effective method of producing and purifying mass quantities of mRNA. To enable a sufficient supply of mRNA for use as a therapeutic, CureVac's scientists developed new methods to purify the mRNA, as well as the DNA template which encodes the mRNA, using a technique called Tangential Flow Filtration ("TFF"). In 2015, CureVac filed its first patent application directed to this advance in mRNA technology.

ANSWER: BioNTech and Pfizer admit the information in the first sentence of Paragraph 23 was known as early as 2000. BioNTech and Pfizer deny the remaining allegations of Paragraph 23.

24. On September 1, 2020, the U.S. Patent & Trademark Office issued U.S. Patent No. 10,760,070 ("the '070 patent") titled "Method for producing and purifying RNA, comprising at least one step of tangential flow filtration." A true and correct copy of the '070 patent is attached as Exhibit 5. On June 6, 2023, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,667,910 ("the '910 patent") titled "Method for producing and purifying RNA, comprising at least one step of tangential flow filtration." A true and correct copy of the '910 patent is attached as Exhibit 6. The '070 and '910 patents list Andreas Funkner, Stefanie Dorner, Stefanie Sewing, Johannes Kamm, Norbert Broghammer, Thomas Ketterer, and Thorsten Mutzke as inventors.

ANSWER: BioNTech and Pfizer admit that the '070 and '910 patents, on their face, are titled "Method for producing and purifying RNA, comprising at least one step of tangential flow filtration" and list Andreas Funkner, Stefanie Dorner, Stefanie Sewing, Johannes Kamm, Norbert Broghammer, Thomas Ketterer, and Thorsten Mutzke as inventors. BioNTech and Pfizer admit

[4] CureVac's the First Amended Counterclaims did not include paragraph number 22. (*See* D.I. 106 at ¶¶ 21 and 23.)

that Exhibits 5 and 6 are documents that purport to be copies of the '070 and '910 patents. BioNTech and Pfizer deny any remaining allegations of Paragraph 24.

25. Following Dr. Hoerr's groundbreaking discovery in 1999 that "naked" mRNA could generate an immune response in an organism, CureVac scientists spent two decades conducting foundational research to develop methods of delivering mRNA into cells to safely maximize the immune response. In 2014, working with its partners, CureVac began an extensive program to improve the delivery system for its mRNA medicines. That program resulted in the selection of a "lipid nanoparticle" ("LNP") containing an mRNA complexed with an ionizable cationic lipid; distearoylphosphatidylcholine; cholesterol; and a polyethylene glycol-appended lipid. The selection of that delivery mechanism from amongst all those tested by CureVac was validated in a first-in-humans Phase I clinical trial of an mRNA vaccine against rabies.

ANSWER: BioNTech and Pfizer are not aware of any "groundbreaking discovery in 1999" that CureVac has made in the field of mRNA technology. BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 25 and therefore deny them.

26. When the COVID-19 pandemic struck, CureVac scientists leveraged their resources and expertise to find the optimal mRNA sequence encoding the full-length COVID-19 spike protein, and packaged that mRNA in the LNP that resulted from CureVac's selection and validation process in the human rabies vaccine trial. In 2020, CureVac filed its first patent application directed to this advance in mRNA technology.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 26.

27. On February 8, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,241,493 ("the '493 patent") titled "Coronavirus vaccine." A true and correct copy of the '493 patent is attached as Exhibit 7. On October 18, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,471,525 ("the '525 patent") titled "Coronavirus vaccine." A true and correct copy of the '525 patent is attached as Exhibit 8. On February 14, 2023, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,576,966 ("the '966 patent") titled "Coronavirus vaccine." A true and correct copy of the '966 patent is attached as Exhibit 9. On March 7, 2023, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,596,686 ("the '686 patent") titled "Coronavirus vaccine." A true and correct copy of the '686 patent is attached as Exhibit 10. The '493, '525, '966, and '686 patents list Susanne Rauch, Hans Wolfgang Grosse, and Benjamin Petsch as inventors. On March 24, 2023, CureVac petitioned the U.S. Patent & Trademark Office to correct the '493 and '525 patents by adding Mariola Fotin-Mleczek, Patrick Baumhof, and Regina Heidenreich as inventors. True and correct copies of the petitions are attached as Exhibit 11 and Exhibit 12. On May 31, 2023, the U.S. Patent & Trademark Office granted those petitions. True and correct copies of the actions granting those petitions are attached as Exhibit 13 and Exhibit 14.

ANSWER: BioNTech and Pfizer admit that the '493, '525, '966, and '686 patents, on their face, are titled "Coronavirus vaccine" and list Susanne Rauch, Hans Wolfgang Grosse, and Benjamin Petsch as inventors. BioNTech and Pfizer admit that Exhibits 7, 8, 9, and 10 are documents that purports to be a copy of the '493, '525, '966, and '686 patents. BioNTech and Pfizer admit that Exhibits 11 and 12 are documents that purport to add Mariola Fotin-Mleczek, Patrick Baumhof, and Regina Heidenreich as inventors. BioNTech and Pfizer admit that Exhibits 13 and 14 purport to be Patent Office communications regarding Application Nos. 17/231,261 and 17/546,414, respectively, that grant the petitions to correct inventorship. BioNTech and Pfizer deny any remaining allegations of Paragraph 27.

28. CureVac SE owns the '312, '278, '492, '920, '493, '525, '966, and '686 patents. CureVac Manufacturing GmbH owns the '070 and '910 patents.

ANSWER: BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 28 and therefore deny them.

COMIRNATY® (TOZINAMERAN)

29. On information and belief, prior to the emergence of COVID-19, Pfizer and BioNTech had begun researching an mRNA vaccine for influenza, but lacked expertise in developing mRNA vaccines for coronaviruses and other infectious diseases. Indeed, BioNTech's CEO, Uğur Şahin, was reported to have said that infectious disease targets were "not a priority" for his company before COVID-19.

ANSWER: BioNTech and Pfizer admit that they began work on an influenza vaccine using mRNA before COVID-19, but otherwise deny the allegations of the first sentence of Paragraph 29. BioNTech and Pfizer admit that Uğur Şahin was quoted in a *Nature* article, which speaks for itself.[5] BioNTech and Pfizer otherwise deny the allegations of the second sentence of Paragraph 29.

[5] Asher Mullard, *COVID-19 Vaccine Success Enables a Bolder Vision for mRNA Cancer Vaccines, Says BioNTech CEO*, 20 NATURE REVS.: DRUG DISCOVERY 500 (Jun. 17, 2021), https://www.nature.com/articles/d41573-021-00110-x.

30. According to news reports, Pfizer apparently lacked any mRNA candidates in clinical trials before COVID-19, and BioNTech did not have any such candidates in clinical trials for infectious diseases. Although Pfizer and BioNTech started their development of an mRNA vaccine for COVID-19 after such programs began at other companies, they quickly made-up ground by utilizing CureVac's patented inventions, albeit without a license from CureVac to do so.

ANSWER: BioNTech and Pfizer deny the allegations in Paragraph 30. BioNTech and Pfizer also deny the allegations of the first sentence of Paragraph 30 on the basis that the term "news reports" is vague.

31. Pfizer and BioNTech had many choices for how they could design their COVID-19 vaccine. Indeed, on information and belief, Pfizer and BioNTech's COVID-19 vaccine program—"Project Lightspeed"—started with more than twenty vaccine candidates representing different mRNA constructs and target antigens that BioNTech took into preclinical testing. As they got further along in their clinical development, they ultimately focused exclusively on vaccine designs that used CureVac's patented technologies. By April 23, 2020, they had narrowed their effort to four candidates.

ANSWER: BioNTech and Pfizer admit that BioNTech made choices in the design of a COVID-19 vaccine, but otherwise deny the allegations in the first sentence of Paragraph 31. BioNTech and Pfizer admit that their vaccine program was internally dubbed "Project Lightspeed." BioNTech and Pfizer admit that on April 22, 2020, Pfizer issued a press release, which speaks for itself.[6] BioNTech and Pfizer deny any remaining allegations of Paragraph 31.

32. On July 27, 2020, Pfizer and BioNTech announced they had chosen to advance a single COVID-19 vaccine candidate called "BNT162b2" to a Phase II/III clinical trial. On information and belief, BNT162b2 is for all relevant purposes identical to the Comirnaty® product. On information and belief, the vaccine candidate called "BNT162b2" was given the recommended name "tozinameran" in the World Health Organization's register of International Nonproprietary Names for Pharmaceutical Substances.

[6] Pfizer, *Press Release: BioNTech and Pfizer announce regulatory approval from German authority Paul-Ehrlich-Institut to commence first clinical trial of COVID-19 vaccine candidates*, https://www.pfizer.com/news/press-release/press-release-detail/biontech_and_pfizer_announce_regulatory_approval_from_german_authority_paul_ehrlich_institut_to_commence_first_clinical_trial_of_covid_19_vaccine_candidates.

ANSWER: BioNTech and Pfizer admit that on July 27, 2020, BioNTech and Pfizer began a Phase 2/3 clinical study of their advanced nucleoside-modified messenger RNA candidate BNT162b2. The allegations of the second sentence of Paragraph 32 are vague as to the precise "relevant purposes," and BioNTech and Pfizer also deny the allegations on that basis. BioNTech and Pfizer also admit that the World Health Organization's register of International Nonproprietary Names for Pharmaceutical Substances speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 32.

33. Pfizer and BioNTech's strategy of using CureVac's inventions was very successful, resulting in the approval to market Comirnaty® (tozinameran).[7] On December 11, 2020, the FDA granted an Emergency Use Authorization ("EUA") for the use of BNT162b2 (later renamed Comirnaty® (tozinameran)) in individuals over 16 years of age. On August 23, 2021, the FDA approved the BLA for Comirnaty® (BNT162b2) for use in individuals over 16 years of age. On October 29, 2021, the FDA authorized the use of Comirnaty® (tozinameran) in children between 5 and 11 years of age pursuant to an EUA. On September 22, 2021, the FDA amended the EUA for Comirnaty® (tozinameran) to permit administration of a booster dose in certain individuals six months after completing their primary two-dose series with Comirnaty®. On November 19, 2021, the FDA expanded the EUA to permit a booster dose of Comirnaty® (tozinameran) for individuals who are at least 18 years old and allowed for the administration of a Comirnaty® (tozinameran) booster in individuals who completed their primary vaccination series with any FDA-authorized or approved COVID-19 vaccine. The FDA further expanded the EUA to permit a booster dose of Comirnaty® (tozinameran) in 16- and 17-year-olds on December 9, 2021, and for individuals 12-years-old or older on January 3, 2022. On January 3, 2022, the FDA also shortened the time period for administration of the third booster dose of Comirnaty® (tozinameran) to five months after completion of the primary vaccination series. On March 29, 2022, the FDA authorized individuals who are over the age of 50 or immunocompromised patients who are 12 years old or older to receive a second booster dose of Comirnaty® (tozinameran) four months after receiving a first booster dose. On May 17, 2022, the FDA expanded the use of Comirnaty® (tozinameran) as a single booster dose for administration to individuals 5 through 11 years of age at least five months after completion of a primary vaccination series. On June 17, 2022, the FDA expanded the EUA for Comirnaty® (tozinameran) to include the use of the vaccine in individuals between six months and 4 years of age.

[7] For ease of reference, we refer herein to the original version of Comirnaty as "Comirnaty® (tozinameran)."

ANSWER: BioNTech and Pfizer deny the allegations of the first sentence of Paragraph 33. BioNTech and Pfizer admit the allegations of the second through eleventh sentences of Paragraph 33. BioNTech and Pfizer deny any remaining allegations of Paragraph 33.

34. On information and belief, on August 23, 2021, BioNTech received full approval to market Comirnaty® (tozinameran) in the United States. According to the Comirnaty® (tozinameran) package insert, "Comirnaty is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)." Exhibit 15 (Comirnaty® package insert) at 1. The active ingredient in Comirnaty® (tozinameran) is tozinameran, an mRNA that encodes the viral spike glycoprotein on SARS-CoV-2. Exhibit 15 (Comirnaty® package insert) at 14. Tozinameran contains five elements: (1) a modified 5' cap (a chemically modified form of the nucleotide guanosine triphosphate); (2) a 5' untranslated region (a leader sequence); (3) an S glycoprotein signal peptide (an extended leader sequence); (4) a "codon-optimized sequence" encoding the full-length SARS-CoV-2 spike (S) glycoprotein containing mutations modifying two positions so that they are translated to incorporate prolines; and (5) a 3' untranslated region that includes a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 16 (WHO INN Programme Report No. 11889) at 1-2. When tozinameran is transcribed from its DNA plasmid, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. *Id*. at 2-4.

ANSWER: BioNTech and Pfizer admit the first sentence of Paragraph 34. BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 34.

COMIRNATY® (TOZINAMERAN AND FAMTOZINAMERAN)

35. On August 22, 2022, Pfizer and BioNTech submitted an application to the FDA seeking to amend the EUA to authorize bivalent formulations of Comirnaty® that includes tozinameran and a second mRNA that encodes a protein designed to mimic the SARS-CoV-2 spike (S) glycoprotein on the Omicron BA.4 and BA.5 virus variants. The second mRNA included in this version of Comirnaty® was given the recommended name "famtozinameran" in the World Health Organization's register of International Nonproprietary Names for Pharmaceutical Substances.

ANSWER: BioNTech and Pfizer admit that on August 22, 2023 they announced that they submitted an application to the FDA for Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine. BioNTech and Pfizer also admit that the World Health Organization's register of International Nonproprietary Names for Pharmaceutical Substances speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 35.

36. On August 31, 2022, the FDA amended the EUA to authorize the use of Comirnaty® (tozinameran and famtozinameran)[8] for use as a single booster dose at least two months following primary or booster vaccination. Exhibit 17 (Comirnaty® Bivalent package insert) at 16. The active ingredients in Comirnaty® (tozinameran and famtozinameran) are tozinameran and famtozinameran, which are mRNAs that encode the viral spike glycoprotein on SARS-CoV-2. Exhibit 17 (Comirnaty® Bivalent package insert) at 16. Tozinameran and famtozinameran contain five elements: (1) a modified 5' cap (a chemically modified form of the nucleotide guanosine triphosphate); (2) a 5' untranslated region (a leader sequence); (3) an S glycoprotein signal peptide (an extended leader sequence); (4) a "codon-optimized sequence" encoding the full-length SARS-CoV-2 spike (S) glycoprotein containing mutations modifying two positions so that they are translated to incorporate prolines; and (5) a 3' untranslated region that includes a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 16 (WHO INN Programme Report No. 11889) at 1-2; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)"). When tozinameran and famtozinameran are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 16 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

ANSWER: BioNTech and Pfizer admit the first sentence of Paragraph 36. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron

[8] For ease of reference, we refer herein to the bivalent form of Comirnaty as "Comirnaty® (tozinameran and famtozinameran)."

(BA.4/BA.5) Variant," which speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 36.

37. On December 8, 2022, the FDA amended the EUA to authorize Comirnaty® (tozinameran and famtozinameran) for use as a single booster dose in children down to 6 months of age. On March 14, 2023, the FDA amended the EUA to authorize Comirnaty® (tozinameran and famtozinameran) for use in children six months through four years of age at least two months after completion of primary vaccination series with three doses of Comirnaty® (tozinameran). On April 18, 2023, the FDA amended the EUA to authorize Comirnaty® (tozinameran and famtozinameran) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. As of April 18, 2023, the monovalent Comirnaty® (tozinameran) is no longer authorized for use in the United States.

ANSWER: BioNTech and Pfizer admit the allegations of paragraph 37.

COMIRNATY® (RAXTOZINAMERAN)

38. On information and belief, on June 23, 2023, Pfizer and BioNTech submitted regulatory applications to the FDA seeking approval to market a new monovalent form of Comirnaty® containing an mRNA that encodes a protein designed to mimic the SARS-CoV-2 spike (S) glycoprotein on the Omicron XBB.1.5 virus variant for individuals 6 months of age and older. *See* Exhibit 19 (June 23 Press Release) at 1. On information and belief, the mRNA included in this version of Comirnaty® was designated as "2887554-49-4" in the registry of the Chemical Abstracts Service and was given the recommended name "raxtozinameran" in the World Health Organization's register of International Nonproprietary Names for Pharmaceutical Substances.[9] *See* Exhibit 20 (WHO INN Programme Report June 30, 2023) at 3. On information and belief, the sequence corresponding to raxtozinameran was published by the Chemical Abstracts Service, Chemical Abstracts Service (CAS), a division of the American Chemical Society. *See* Exhibit 21 (CAS Reg. No. 2887554-49-4).

ANSWER: BioNTech and Pfizer admit that Exhibit 19 to CureVac's counterclaims is a document that purports to be "Pfizer and BioNTech Submit Applications to U.S. FDA for Omicron XBB.1.5-Adapted Monovalent COVID-19 Vaccine," which speaks for itself. BioNTech and Pfizer admit that Exhibit 20 to CureVac's counterclaims is a document that purports to be "WHO Drug Information, Vol. 37, No. 2, 2023," which speaks for itself. BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY

[9] For ease of reference, we refer herein to this version of Comirnaty as "Comirnaty® (raxtozinameran)," and to the mRNA contained within this version of Comirnaty® as "raxtozinameran."

COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations in paragraph 38.

39. Pfizer and BioNTech have manufactured Comirnaty® (raxtozinameran) "to ensure readiness ahead of the fall and winter season," and pending approval, Pfizer and BioNTech will be "ready to ship" Comirnaty® (raxtozinameran) "immediately." Exhibit 19 (June 23 Press Release) at 1. According to BioNTech's Chief Executive Officer, Ugur Sahin, BioNTech anticipates approval of Comirnaty® (raxtozinameran) by the end of the summer to allow for a seasonal vaccination campaign to start in early autumn. *See* https://www.reuters.com/business/healthcare-pharmaceuticals/biontech-is-proceeding-with-covid-shot-line-with-who-guidance-2023-05-25/ (available in archival form at https://perma.cc/PZT6-PUXJ). Moreover, Dr. Sahin said that Pfizer and BioNTech will introduce Comirnaty® (raxtozinameran) in the form of a ready-to-use single dose. *Id.*

ANSWER: BioNTech and Pfizer admit that Exhibit 19 to CureVac's counterclaims is a document that purports to be "Pfizer and BioNTech Submit Applications to U.S. FDA for Omicron XBB.1.5-Adapted Monovalent COVID-19 Vaccine," which speaks for itself. BioNTech and Pfizer deny any remaining allegations in paragraph 39.

40. On information and belief, raxtozinameran contains five elements: (1) a modified 5' cap (a chemically modified form of the nucleotide guanosine triphosphate); (2) a 5' untranslated region (a leader sequence); (3) an S glycoprotein signal peptide (an extended leader sequence); (4) a "codon-optimized sequence" encoding the full-length SARS-CoV-2 spike (S) glycoprotein containing mutations modifying two positions so that they are translated to incorporate prolines; and (5) a 3' untranslated region that includes a 110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. Exhibit 21 (CAS Reg. No. 2887554-49-4) at 1–2.

ANSWER: BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations in paragraph 40.

41. On information and belief, Pfizer and BioNTech will receive FDA approval to market Comirnaty® (raxtozinameran) and will market Comirnaty® (raxtozinameran) by the fall of 2023. Accordingly, CureVac seeks a declaration that Comirnaty® (raxtozinameran) infringes one or more claims of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents, respectively.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 41.

PFIZER AND BIONTECH'S FINANCIAL WINDFALL FROM COMIRNATY®[10]

42. Pfizer and BioNTech have enjoyed a financial windfall from their use of CureVac's patented technologies. To date, Pfizer and BioNTech have provided over 591 million doses of Comirnaty® for use in the United States. *See* https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (available in archival form at https://perma.cc/2Y4U-KPSU). Pfizer reported that the COVID-19 vaccine generated $36.7 billion in revenue in 2021, $7.8 billion of which resulted from U.S. sales. *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-fourth-quarter-and-full-year-2021-results at 35 (available in archival form at https://perma.cc/87HM-CLFW). Pfizer recently reported that Comirnaty® generated $37.806 billion in revenue in 2022, $8.775 billion of which resulted from U.S. sales. *See* https://s28.q4cdn.com/781576035/files/doc_financials/2022/q4/Pfizer-10-K.pdf at 38 (available in archival form at https://perma.cc/93VM-QA4D). In 2021, BioNTech reported €18.874 billion in revenue, of which €15.5 billion was recognized from Comirnaty®, of which €14.636 billion was recognized revenues in the United States. https://investors.biontech.de/static-files/a159ee32-cca9-4cea-8460-67dfaa289c39 at 141 (available in archival form at https://perma.cc/43Y2-8W7K). In 2022, BioNTech reported €17.194 billion in revenue, of which €13.79 billion was recognized from Comirnaty®, of which €12.709 billion was recognized revenues in the United States. *See* https://investors.biontech.de/static-files/4e7e11ad-14dd-4b8b-9ad8-5500c6681b4a at 141 (available in archival form at https://perma.cc/SPR2-AUAV).

ANSWER: BioNTech and Pfizer admit that they have released financial reports, which speak for themselves, but deny any remaining allegations in Paragraph 42.

43. Pfizer and BioNTech have made clear that they intend to continue to reap profits from their use of CureVac's patented technologies, including by making product in the United States to serve the global market. For example, in December 2021, the Committee for Medicinal Products for Human Use of the European Medicines Agency approved Pfizer and BioNTech's request to scale up production of Comirnaty® at Pfizer's facility in Andover, Massachusetts "to support the continued supply of Comirnaty in the European Union." *See* https://www.ema.europa.eu/en/news/increase-manufacturing-capacity-covid-19-vaccines-janssen-moderna-biontech-pfizer (available in archival form at httpbs://perma.cc/KDJ5-3PJF).

[10] In the following paragraphs, the use of the term "Comirnaty®" without reference to a specific version of Pfizer and BioNTech's COVID-19 vaccine refers to all versions of Pfizer and BioNTech's COVID-19 vaccine: Comirnaty® (tozinameran), Comirnaty® (tozinameran and famtozinameran), and Comirnaty® (raxtozinameran), as described above; and when referring to the mRNA(s) present in each version of Comirnaty®, the following paragraphs will use the terms tozinameran, famtozinameran, and raxtozinameran, as described above.

ANSWER: BioNTech and Pfizer admit that the European Medicines Agency ("EMA") has made statements about Comirnaty®, which speak for themselves, but deny any remaining allegations of Paragraph 43.

44. Pfizer and BioNTech have also made clear that they intend to sell additional booster doses of Comirnaty®. For example, on March 29, 2022, the FDA authorized certain people to receive a second booster dose of Comirnaty®. Pfizer and BioNTech actively promote the use of booster doses of Comirnaty®, including through their website for Comirnaty®: https://www.comirnaty.com/booster-dose/ (available in archival form at https://perma.cc/7WHG-LZ3B).

ANSWER: BioNTech and Pfizer admit that they maintain a website at https://www.comirnaty.com, which speaks for itself. BioNTech and Pfizer admit that on March 29, 2022, the FDA authorized second booster doses of their COVID-19 vaccine in certain individuals. BioNTech and Pfizer deny any remaining allegations of Paragraph 44.

45. All Comirnaty® made and administered in the United States was distributed by Pfizer to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. *See* https://cdn.pfizer.com/pfizercom/Pfizer_PGS_COVID-19_Factsheet_071122.pdf (available in archival form at https://perma.cc/36BC-E5AP). All Comirnaty® administered in the United States was manufactured in the United States. *Id.*

ANSWER: BioNTech and Pfizer admit that Pfizer maintains a website at https://cdn.pfizer.com, which speaks for itself. BioNTech and Pfizer deny any remaining allegations of Paragraph 45.

46. In recognition of the need for ensuring access to the accused vaccines, CureVac is not seeking the removal of Comirnaty® from the market or to prevent its future sale. CureVac brings these counterclaims for patent infringement so that it may obtain fair compensation for Pfizer and BioNTech's past and continued use of CureVac's patented technologies. That fair compensation will translate into an opportunity for CureVac to reinvest in its leading mRNA platform.

ANSWER: BioNTech and Pfizer admit that there is a need for ensuring access to Comirnaty®, and that CureVac represents that it is not seeking the removal of Comirnaty® from

the market or to prevent its future sale. BioNTech and Pfizer deny the remaining allegations of Paragraph 46 and deny that CureVac is entitled to any compensation whatsoever.

COUNT I – INFRINGEMENT OF THE '312 PATENT

47. CureVac incorporates each of the above paragraphs 1–46 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

48. The '312 patent is directed to methods for stabilizing mRNA molecules by altering the coding sequence. The '312 patent inventors discovered that increasing the content of guanine and cytosine residues ("the G/C content") in the coding sequence of an mRNA increases its stability and allows for increased polypeptide production from the mRNA.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 48.

49. The '312 patent issued with sixteen claims. Claim 1, the only independent claim, recites:

> **1**. A method for producing a stabilized mRNA molecule encoding a polypeptide, wherein the stabilized mRNA molecule encoding the polypeptide comprises a coding sequence that has an increased Guanine/Cytosine (G/C) content relative to the original coding sequence encoding the polypeptide, said relative G/C content being increased by at least 7 percentage points compared to the original coding sequence encoding the polypeptide, to thereby produce a stabilized mRNA molecule, wherein said increase in relative G/C content results in the elimination of at least one destabilizing sequence element (DSE), wherein the stabilized mRNA molecule Exhibits enhanced expression of the polypeptide compared to mRNA having the original coding sequence encoding the polypeptide.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '312 patent includes the above language but deny that any of the sixteen issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 49.

50. Dependent claims 7–9 serially narrow claim 1:

> **7**. The method of claim 1, wherein synthesizing the stabilized mRNA comprises producing a DNA molecule encoding the stabilized mRNA.
>
> **8**. The method of claim 7, wherein synthesizing the stabilized mRNA further comprises transcribing the stabilized mRNA from the DNA molecule.

9. The method of claim 8, wherein the transcription is in vitro transcription.

ANSWER: BioNTech and Pfizer admit that claims 7–9 of the '312 patent includes the above language but deny any remaining allegations of paragraph 50.

51. Claim 14 depends from claim 1, and recites:

14. The method of claim 1, further comprising the formulating the stabilized mRNA into a pharmaceutically acceptable carrier.

ANSWER: BioNTech and Pfizer admit that claim 14 includes the above language but deny that it claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 51.

52. Claim 15 depends from claim 1, and recites:

15. The method of claim 1, further comprising synthesizing a stabilized mRNA comprising at least one nucleotide position replaced with a nucleotide analogue.

ANSWER: BioNTech and Pfizer admit that claim 15 includes the above language but deny that it claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 52.

53. On information and belief, the method Pfizer and BioNTech (the "Counterclaim Defendants") have used and continue to use to manufacture Comirnaty® satisfies each and every element of at least claims 1, 7–9, 14, and 15 in the '312 patent. Counterclaim Defendants' actions with respect to Comirnaty® have thus infringed at least these claims in the '312 patent.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 53.

54. On information and belief, the coding sequences of the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® each have a G/C content that is increased by at least 7 percentage points compared to the original coding sequence encoding the spike glycoprotein on SARS-CoV-2, and is (1) more stable (*i.e.*, indicating that at least one destabilizing sequence element has been eliminated) and (2) provides enhanced expression of the spike glycoprotein as compared to the original coding sequence. Counterclaim Defendants' manufacture of Comirnaty® therefore infringes claim 1 of the '312 patent.

ANSWER: Paragraph 54 appears to include language from claim 1 of the '312 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a

response is required, BioNTech and Pfizer deny the allegations of Paragraph 54 and deny that the manufacture of any version of Comirnaty® infringes any claim of the '312 patent.

55. On information and belief, Counterclaim Defendants make the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® by producing a template DNA molecule encoding tozinameran, famtozinameran, or raxtozinameran, respectively, followed by the *in vitro* transcription of the template DNA molecule to produce tozinameran, famtozinameran, or raxtozinameran. Counterclaim Defendants' manufacture of Comirnaty® therefore infringes claims 7, 8, and 9 of the '312 patent.

ANSWER: Paragraph 55 appears to include language from claims 7, 8, and 9 of the '312 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 55 and deny that the manufacture of any version of Comirnaty® infringes any claim of the '312 patent.

56. On information and belief, Comirnaty® is formulated with a pharmaceutically acceptable carrier. Exhibit 15 (Comirnaty® package insert) at 15; Exhibit 17 (Comirnaty® Bivalent package insert) at 36. On information and belief, Counterclaim Defendants instruct those administering Comirnaty® to dilute the Comirnaty® formulation with a solution of 0.9% sodium chloride. Exhibit 15 (Comirnaty® package insert) at 2. Counterclaim Defendants' manufacture and sale of Comirnaty® therefore infringes claim 14 of the '312 patent.

ANSWER: Paragraph 56 appears to include language from claim 14 of the '312 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 56 and deny that the manufacture and sale of any version of Comirnaty® infringes any claim of the '312 patent.

57. On information and belief, when the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 16 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3. Accordingly, Comirnaty® contains a stabilized mRNA comprising at least one nucleotide (uridine) replaced with a nucleotide analog (pseudoU). Counterclaim Defendants' manufacture of Comirnaty® therefore infringes claim 15 of the '312 patent.

ANSWER: Paragraph 57 appears to include language from claim 15 of the '312 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a

response is required, BioNTech and Pfizer deny the allegations of Paragraph 57 and deny that the manufacture of any version of Comirnaty® infringes any claim of the '312 patent.

58. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 7–9, 14, and 15 of the '312 patent, either literally or under the doctrine of equivalents, by manufacturing tozinameran, famtozinameran, and raxtozinameran in the United States for use in Comirnaty® sold in the United States and outside the United States in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 58.

59. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of claim 14 of the '312 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to formulate Comirnaty® in the United States and in this District in a manner that directly infringes claim 14 of the '312 patent in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 59.

60. On information and belief, Comirnaty® constitutes a material part of the invention recited in claim 14 of the '312 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe claim 14 of the '312 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or Emergency Use Authorization in the United States and in this District by others, including healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe claim 14 of the '312 patent in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 60.

61. On information and belief, Counterclaim Defendants have infringed or will infringe one or more of the claims of the '312 patent, either literally or under the doctrine of equivalents, by importing Comirnaty® into the United States in violation of 35 U.S.C. § 271(g).

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 61.

62. Counterclaim Defendants' infringement of the '312 patent has been and continues to be willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it contains an mRNA that has a G/C content that is increased by at least 7 percentage points compared to the original coding sequence encoding the spike glycoprotein on SARS-CoV-2. On March 4, 2014, CureVac granted BioNTech a limited non-exclusive license (that excludes uses related to infectious diseases) to patents and patent applications that include the '312 patent. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '312 patent. D.I. 47 at 12.

ANSWER: BioNTech and Pfizer admit that CureVac granted BioNTech a non-exclusive license effective as of March 4, 2014 with respect to the "Licensed P003 Patents." BioNTech and Pfizer deny the remaining allegations of Paragraph 62.

63. Counterclaim Defendants continue to use the inventions claimed in the '312 patent in deliberate disregard for CureVac's patent rights.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 63.

64. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '312 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Counterclaim Defendants' infringement of the '312 patent.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 64.

65. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '312 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 65.

66. Counterclaim Defendants' conduct with respect to the '312 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 66.

COUNT II – INFRINGEMENT OF THE '312 PATENT (PROVISIONAL RIGHTS)

67. CureVac incorporates each of the above paragraphs 1–66 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

68. The '312 patent issued from U.S. Patent Application No. 14/487,425 ("the '425 application") filed on September 16, 2014, which was filed as a division of Application No. 10/729,830 ("the '830 application") filed on December 5, 2003, which issued as U.S. Patent No. 10,188,748 ("the '748 patent"). The '830 application was filed as a continuation-in-part of an international application, PCT Application No. PCT/EP02/06180 ("the '180 PCT application"), which was filed on June 5, 2002.

ANSWER: BioNTech and Pfizer admit the face of the '312 Patent lists U.S. Patent Application No. 14/487,425 filed on September 16, 2014, and "division of application

No. 10/729,830 filed on Dec. 5, 2003, now Pat. No. 10,188,748, which is a continuation-in-part of application No. PCT/EP02/06180, filed on Jun. 5, 2002." BioNTech and Pfizer deny any remaining allegations of paragraph 68 and deny that CureVac is entitled to any provisional rights whatsoever.

69. Pursuant to 35 U.S.C. § 122(b), the '425 application published as U.S. Patent Publ. No. 2015/0104476 A1 ("the '476 publication") on April 16, 2015. A true and correct copy of the '476 publication is attached hereto as Exhibit 22. The '476 publication contained 17 claims, numbered 29 to 45. Claims 29 and 34 recite:

> **29**. A method for producing a stabilized mRNA comprising synthesizing an mRNA encoding a native polypeptide sequence, wherein the mRNA encoding the polypeptide comprises a nucleic acid sequence that has an increased GuanineCytosine (G/C) content relative to the native nucleic acid sequence encoding the polypeptide, said relative G/C content being increased by at least 7 percentage points compared to native nucleic acid sequence encoding the polypeptide, to thereby produce a stabilized mRNA.
>
> **34**. The method of claim 29, wherein the stabilized mRNA comprises a nucleic acid sequence having at least one destabilizing sequence element (DSE) removed relative to the native mRNA encoding the polypeptide.

ANSWER: BioNTech and Pfizer admit the face of the '312 Patent lists U.S. Patent Application No. 14/487,425 filed on September 16, 2014, and lists U.S. Patent Publ. No. 2015/0104476 A1 as "Prior Publication Data." BioNTech and Pfizer admit that Exhibit 22 to CureVac's counterclaims is a document that purports to be U.S. Patent Publ. No. 2015/0104476 A1, which includes 17 claims numbered 29 to 45, including the text for claims 29 and 34 included above. BioNTech and Pfizer deny any remaining allegations of paragraph 69.

70. On March 4, 2014, CureVac granted BioNTech a limited non-exclusive license (that excludes uses related to infectious diseases) to patents and patent applications that include the application that published as the '476 publication. Thus, on information and belief, BioNTech had actual notice of the '476 publication. On information and belief, as a collaboration partner of BioNTech, Pfizer also had actual notice of the '476 publication.

ANSWER: The allegations of Paragraph 70 purport to characterize a document from March 4, 2014, and set forth legal conclusions, to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 70.

71. On information and belief, the method which Counterclaim Defendants have used to manufacture Comirnaty® satisfies each and every element of at least claim 34 in the '476 publication. Counterclaim Defendants' actions with respect to Comirnaty® thus infringed at least claim 34 in the '476 publication under 35 U.S.C. §154(d).

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 71.

72. On information and belief, the coding sequences of the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® each have a G/C content that is increased by at least 7 percentage points compared to their corresponding original coding sequences for the spike glycoprotein on SARS-CoV-2, and tozinameran, famtozinameran, and raxtozinameran are more stable than their corresponding original coding sequences due to the removal of at least one destabilizing sequence element. Counterclaim Defendants' manufacture of Comirnaty® therefore infringed claim 34 in the '476 publication under 35 U.S.C. §154(d).

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 72.

73. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of claim 34 in the '476 publication. CureVac is entitled to an award of a reasonable royalty for Counterclaim Defendants' infringement of claim 34 in the '476 publication.

ANSWER: BioNTech and Pfizer deny the allegations of Paragraph 73.

COUNT III – INFRINGEMENT OF THE '278 PATENT

74. CureVac incorporates each of the above paragraphs 1–73 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

75. The '278 patent is directed to methods of treating or preventing infectious diseases by administering an RNA having a unique poly-adenosine ("poly(A)") tail that results in the increased expression of the protein encoded by the RNA. The '278 patent inventors discovered that an mRNA containing a 3'-untranslated region with two poly(A) sequences separated by a sequence of from 10 to 90 nucleotides expresses more protein *in vivo* than an mRNA containing a single poly(A) tail. The '278 patent claims encompass administering this kind of mRNA to treat or prevent an infectious disease.

ANSWER: Paragraph 75 appears to include language from the '278 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 75.

76. The '278 patent issued with twenty claims. Independent claim 1 recites:

> **1**. A method for treating or preventing an infectious disease, the method comprising administering an RNA molecule comprising:
>
> a) at least one open reading frame (ORF) encoding an antigen from a pathogen associated with the infectious disease; and
>
> b) a 3′-untranslated region (3′-UTR) comprising at least two poly(A) sequences, wherein at least one of the poly(A) sequences comprises at least 70 adenine nucleotides, wherein the at least two poly (A) sequence elements are separated by a nucleic acid sequence comprising from 10 to 90 nucleotides, wherein the RNA molecule is administered intramuscularly.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '278 patent includes the above language but deny that any of the twenty issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 76.

77. Dependent claims 13–17 serially narrow claim 1:

> **13**. The method of claim 1, wherein the open reading frame is at least partially codon-optimized.
>
> **14**. The method of claim 13, wherein the RNA molecule comprises at least one nucleotide analogue.
>
> **15**. The method of claim 14, wherein the at least one nucleotide analogue is a modified form of uridine.
>
> **16**. The method of claim 15, wherein the modified form of uridine is chemically altered by methylation.
>
> **17**. The method of claim 16, wherein the modified form of uridine is a naturally occurring variant of uridine.

ANSWER: BioNTech and Pfizer admit that claims 13–17 of the '278 patent include the above language but deny any remaining allegations of paragraph 77.

78. Comirnaty® contains mRNA molecules (tozinameran, famtozinameran, and raxtozinameran) that contain an open reading frame (ORF) encoding a SARS CoV-2 viral spike protein antigen. Exhibit 16 (WHO INN Programme Report No. 11889) at 2 ("Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein"); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . .").

ANSWER: Paragraph 78 appears to include language from the '278 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 78 and deny that any version of Comirnaty® infringes any claim of the '278 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 78.

79. The mRNA molecules in Comirnaty® contain a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 16 (WHO INN Programme Report No. 11889) at 1–2; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)").

ANSWER: Paragraph 79 appears to include language from the '278 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 79 and deny that any version of Comirnaty® infringes any claim of the '278 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 79.

80. The use of Comirnaty® as instructed in its package inserts is a method for treating or preventing an infectious disease, involving administering the tozinameran, tozinameran and

famtozinameran, and/or raxtozinameran, which contains the open reading frame (ORF) encoding a SARS CoV-2 viral spike protein antigen, which is from the pathogen SARS-CoV-2 virus associated with the infectious disease COVID-19; and which contains a 3'-untranslated region containing at least two poly(A) sequences, one of which contains 70 adenosine nucleotides, and in which the two poly(A) sequences are separated by 10 nucleotides; and which is administered intramuscularly. For example, Section 2.2 of the Comirnaty® package insert instructs users to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly" (Exhibit 15 (Comirnaty® package insert) at 5), Section 11 states "[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein SARS-CoV-2" (*id*. at 14), and Section 12 states "[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." *Id.* at 15; *see also* Exhibit 17 (Comirnaty® Bivalent package insert) at 17 ("COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use"). Section 12 also states that "[t]he vaccine elicits an immune response to the S antigen, which protects against COVID-19," which constitutes a method for treating or preventing an infectious disease. Exhibit 15 (Comirnaty® package insert) at 15; *see also* Exhibit 17 (Comirnaty® Bivalent package insert) at 17.

ANSWER: Paragraph 80 appears to include language from the '278 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 80 and deny that Comirnaty® infringes any claim of the '278 patent. BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 80.

81. On information and belief, when the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are transcribed from their plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 16 (WHO INN Programme Report No. 11889) at 2–4; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3. In other words, tozinameran, famtozinameran, and raxtozinameran contain an mRNA comprising at least one nucleotide (uridine) replaced with a nucleotide analog (pseudoU) that has been chemically modified by methylation.

ANSWER: Paragraph 81 appears to include language from the '278 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is

required, BioNTech and Pfizer deny the allegations of paragraph 81 and deny that any version of Comirnaty® infringes any claim of the '278 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 81.

82. On information and belief, BioNTech Manufacturing is the BLA license holder for Comirnaty®. Exhibit 23 (FDA Approval Letter) at 1. The use of Comirnaty® as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claims 1 and 13–17 of the '278 patent because the package inserts instruct medical professionals to administer Comirnaty® via an intramuscular injection. Exhibit 15 (Comirnaty® package insert) at 2; Exhibit 17 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1 and 13–17 of the '278 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that directly infringes the '278 patent. Indeed, the only use of Comirnaty® instructed in its package insert infringes the claims of the '278 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '278 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer admit that BioNTech Manufacturing GmbH is the Biologics License Application holder for Comirnaty® in the United States. BioNTech and Pfizer deny the remaining allegations of paragraph 82.

83. Prior to approval of the BLA, the use of Comirnaty® pursuant to all of the Counterclaim Defendants' Emergency Use Authorizations infringed the claims of the '278 patent for the same reasons. For example, Counterclaim Defendants published a "Fact Sheet" that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Counterclaim Defendants' vaccine "has been shown to prevent COVID-19." Exhibit 24 (Fact Sheet) at 4. Booster doses can comprise the administration of a vaccine identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing (available in archival form at https://perma.cc/94KH-

8R2B). Booster doses can also comprise a mixture of 15 micrograms of tozinameran and 15 micrograms of famtozinameran (*i.e.*, Comirnaty® (tozinameran and famtozinameran)) formulated in the same manner as other doses of Comirnaty® (tozinameran). *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE). On information and belief, upon approval, the product label and formulation of Comirnaty® (raxtozinameran) will be identical to Comirnaty® (tozinameran) and Comirnaty® (tozinameran and famtozinameran).

ANSWER: BioNTech and Pfizer deny the allegations of the first sentence of paragraph 83. BioNTech and Pfizer admit that Exhibit 24 to CureVac's counterclaim is a document that purports to be a "Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use in Individuals 12 Years of Age and Older" bearing a revision date of July 8, 2022, which speaks for itself. BioNTech and Pfizer admit that Pfizer maintains a website https://www.pfizer.com, which speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 83.

84. On information and belief, Comirnaty® constitutes a material part of the invention in one or more claims of the '278 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1 and 13–17 of the '278 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package inserts and/or Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '278 patent in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 84.

85. On information and belief, Counterclaim Defendants have knowledge of the '278 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '278 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 85.

86. For example, BioNTech was aware of the applications that led to the '278 patent. On June 26, 2018, BioNTech filed an Information Disclosure Statement in U.S. Patent App. No. 15/217,555, a patent application titled "Modification of RNA, Producing an Increased Transcript

Stability and Translation Efficiency," that listed Patent Cooperation Treaty Application Publ. No. WO 2016/091391 ("the '391 publication"), which is the publication of the application that led to the '278 patent. Exhibit 25 (BioNTech IDS) at 4. ("2016/091391 WO A1 2016-06-16 Curevac AG"). Also on June 26, 2018, BioNTech provided a copy of the '391 publication to the U.S. Patent & Trademark Office. Despite their knowledge of the inventions claimed in the '391 publication, Counterclaim Defendants chose to utilize a 3′-untranslated region (3'-UTR) comprising a poly(A) sequence that contains 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. On information and belief, Counterclaim Defendants knew that choosing that design would infringe claims that would issue from the '391 publication. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '287 patent. D.I. 47 at 12. Counterclaim Defendants' infringement of the '278 patent has thus been willful.

ANSWER: Paragraph 86 appears to include language from the '278 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 86 and deny that any version of Comirnaty® infringes any claim of the '278 patent. BioNTech and Pfizer admit that Exhibit 25 to CureVac's counterclaims is a document that purports to be "INFORMATION DISCLOSURE STATEMENT BY APPLICANT," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 86.

87. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '278 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '278 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 87.

88. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '278 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 88.

89. Counterclaim Defendants' conduct with respect to the '278 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 89.

COUNT IV – INFRINGEMENT OF THE '492 PATENT

90. CureVac incorporates each of the above paragraphs 1–89 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

91. The application that led to the issuance of the '492 patent was filed as a division of the application that led to the '278 patent, and therefore the '492 patent shares a common specification with the '278 patent. The '492 patent, like the '278 patent, is directed to methods of treating or preventing infectious diseases by administering an RNA having a unique poly(A) tail that results in the increased expression of the protein encoded by the RNA.

ANSWER: Paragraph 91 sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 91.

92. The '492 patent issued with thirty claims. Independent claim 25 recites:

> **25**. A method for increasing protein production from a RNA molecule comprising providing the RNA molecule formulated in a pharmaceutical composition, where the RNA molecule comprises:
>
> a) a 5′-cap structure;
>
> b) at least one open reading frame (ORF) encoding a protein; and
>
> c) a heterologous 3′-untranslated region (3′-UTR) comprising at least a first and a second poly(A) sequence, wherein:
>
> (i) the first poly(A) sequence comprises at least 20 adenine nucleotides; and
>
> (ii) the second poly(A) sequence comprises at least 70 adenine nucleotides,
>
> wherein the first and the second poly(A) sequences are separated by a nucleic acid sequence consisting of 10 nucleotides and having no more than 2 consecutive adenine nucleotides,
>
> wherein the ORF encoding the protein has a G/C content that is increased by at least 15% relative to a corresponding reference ORF encoding the protein,
>
> wherein the RNA molecule yields increased protein production when expressed in a cell or an organism in comparison to a reference nucleic acid molecule

comprising an identical nucleic acid sequence as the RNA molecule but lacking a second poly(A) sequence.

ANSWER: BioNTech and Pfizer admit that claim 25 of the '492 patent includes the above language but deny that any of the thirty issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 92.

93. Dependent claims 26–30 serially narrow claim 25:

26. The method of claim 25, wherein the ORF encoding the protein is an antigen.

27. The method of claim 26, wherein the antigen is a viral antigen.

28. The method of claim 27, wherein the RNA molecule comprises at least one nucleotide analogue, which is a naturally occurring variant of uridine.

29. The method of claim 28, wherein the RNA molecule is complexed with a cationic carrier or a polycationic carrier.

30. The method of claim 29, wherein the cationic or polycationic compound comprises a cationic lipid.

ANSWER: BioNTech and Pfizer admit that claims 26–30 of the '492 patent include the above language but deny any remaining allegations of paragraph 93.

94. Comirnaty® contains tozinameran, famtozinameran, and/or raxtozinameran, each of which is an mRNA molecule that contains a "cap" at the 5′ end of the molecule. Exhibit 16 (WHO INN Programme Report No. 11889) at 1 ("A modified 5'-cap1 structure (m7G+m3'-5'-ppp-5'-Am)"); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 ("Sequence length: 4269, which includes 'Cap-' to denote the presence of the 5'-cap analog").

ANSWER: Paragraph 94 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 94 and deny that any version of Comirnaty® infringes any claim of the '492 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure

[Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 94.

95. Comirnaty® contains tozinameran, famtozinameran, and/or raxtozinameran, each of which is an mRNA molecule that contains an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen. Exhibit 16 (WHO INN Programme Report No. 11889) at 2 ("Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein"); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . .").

ANSWER: Paragraph 95 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 95 and deny that any version of Comirnaty® infringes any claim of the '492 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 95.

96. Comirnaty® contains tozinameran, famtozinameran, and/or raxtozinameran, each of which is an mRNA molecule that contains a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 16 (WHO INN Programme Report No. 11889) at 1–2; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)"). The sequence of the 10-nucleotide linker is "GCAΨAΨGACΨ." Exhibit 16 (WHO INN Programme Report No. 11889) at 4 (nucleotides 4188 to 4197); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 (nucleotides 4205 to 4214)").

ANSWER: Paragraph 96 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 96 and deny that any version of Comirnaty® infringes any claim of the '492 patent. BioNTech and Pfizer admit that Exhibit 16 to

CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 96.

97. On information and belief, the coding sequences of tozinameran, famtozinameran, and raxtozinameran have a G/C content that is increased by at least 15 percentage points compared to the original coding sequences for their corresponding spike glycoproteins on SARS-CoV-2.

ANSWER: Paragraph 97 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 97 and deny that any version of Comirnaty® infringes any claim of the '492 patent.

98. On information and belief, when Comirnaty® is administered to an organism, the antigen produced by tozinameran, famtozinameran, and raxtozinameran (*i.e.*, a coronavirus spike protein) is produced at a higher level than it would be if Comirnaty® contained tozinameran, famtozinameran, and raxtozinameran lacking the second poly(A).

ANSWER: Paragraph 98 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 98 and deny that any version of Comirnaty® infringes any claim of the '492 patent.

99. On information and belief, when the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, a naturally occurring variant of uridine, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 16 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

ANSWER: Paragraph 99 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is

required, BioNTech and Pfizer deny the allegations of paragraph 99 and deny that any version of Comirnaty® infringes any claim of the '492 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 99.

100. On information and belief, the mRNAs in Comirnaty® are complexed with lipid nanoparticles containing ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), which is also known as "ALC-0315." Exhibit 15 (Comirnaty® package insert) at 15; Exhibit 17 (Comirnaty® Bivalent package insert) at 36. ALC-0315 is a cationic lipid. Exhibit 26 (Rapporteur Review) at 188 ("The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine and two ester moieties").

ANSWER: Paragraph 100 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 100 and deny that any version of Comirnaty® infringes any claim of the '492 patent. BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 100.

101. On information and belief, BioNTech Manufacturing is the BLA license holder for Comirnaty®. Exhibit 23 (FDA Approval Letter) at 1. The use of Comirnaty® as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claims 25–30 of the '492 patent. Counterclaim Defendants' package inserts instruct medical

professionals to administer Comirnaty® via an intramuscular injection. Exhibit 15 (Comirnaty® package insert) at 2; Exhibit 17 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 25–30 of the '492 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that directly infringes the claims in the '492 patent. Indeed, the only use of Comirnaty® instructed in its package inserts infringes the claims of the '492 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '492 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer admit that BioNTech Manufacturing GmbH is the Biologics License Application holder for Comirnaty® in the United States. BioNTech and Pfizer deny the remaining allegations of paragraph 101.

102. Prior to approval of the BLA, the use of Comirnaty® pursuant to all of Counterclaim Defendants' Emergency Use Authorizations infringed the claims of the '492 patent for the same reasons. For example, Counterclaim Defendants published a "Fact Sheet" that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Counterclaim Defendants' vaccine "has been shown to prevent COVID-19." Exhibit 24 (Fact Sheet) at 4. Booster doses can comprise the administration of a vaccine identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing (available in archival form at https://perma.cc/94KH-8R2B). Booster doses can also comprise a mixture of 15 micrograms of tozinameran and 15 micrograms of famtozinameran (*i.e.*, Comirnaty® (tozinameran and famtozinameran)) formulated in the same manner as other doses of Comirnaty® (tozinameran). *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE). On information and belief, upon approval, the product label and formulation of Comirnaty® (raxtozinameran) will be identical to Comirnaty® (tozinameran) and Comirnaty® (tozinameran and famtozinameran).

ANSWER: BioNTech and Pfizer admit that Exhibit 24 to CureVac's counterclaim is a document that purports to be a "Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use in Individuals 12 Years of Age and Older"

bearing a revision date of July 8, 2022, which speaks for itself. BioNTech and Pfizer admit that Pfizer maintains a website https://www.pfizer.com, which speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 102.

103. On information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '492 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 25–30 of the '492 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package inserts and/or Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '492 patent in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 103.

104. On information and belief, Counterclaim Defendants have knowledge of the '492 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '492 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 104.

105. For example, BioNTech was aware of the applications that led to the '492 patent. On June 26, 2018, BioNTech filed an Information Disclosure Statement in U.S. Patent App. No. 15/217,555, a patent application titled "Modification of RNA, Producing an Increased Transcript Stability and Translation Efficiency," that listed the '391 publication, which is the publication of a related application that led to the '492 patent. Exhibit 25 (BioNTech IDS) at 4. ("2016/091391 WO A1 2016-06-16 Curevac AG"). Also on June 26, 2018, BioNTech provided a copy of the '391 publication to the U.S. Patent & Trademark Office. Despite their knowledge of CureVac's '391 publication, BioNTech and Pfizer chose to utilize a poly(A) sequence that contains 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. On information and belief, BioNTech and Pfizer knew that choosing that poly(A) design would infringe claims that issue from the '391 publication and related applications. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '492 patent. D.I. 47 at 12. Counterclaim Defendants' infringement of the '492 patent has been willful.

ANSWER: Paragraph 105 appears to include language from the '492 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 105 and deny that any version of Comirnaty® infringes any claim of the '492 patent. BioNTech and Pfizer admit that Exhibit 25 to CureVac's counterclaims is a document that purports to be "INFORMATION DISCLOSURE

STATEMENT BY APPLICANT," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 105.

106. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '492 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '492 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 106.

107. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '492 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 107.

108. Counterclaim Defendants' conduct with respect to the '492 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 108.

COUNT V – INFRINGEMENT OF THE '920 PATENT

109. CureVac incorporates each of the above paragraphs 1–108 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

110. The application that led to the issuance of the '920 patent was filed as a division of the application that led to the '492 patent, which was a division of the application that led to the '278 patent. The '920 patent therefore shares a common specification with the '492 and '278 patents. The '920 patent, like the '278 patent, is directed to methods of treating or preventing infectious diseases by administering an RNA having a unique poly(A) tail that results in the increased expression of the protein encoded by the RNA.

ANSWER: Paragraph 110 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 110.

111. The '920 patent issued with twenty-eight claims. Independent claim 23 recites:

> **23**. A method for stimulating an immune response in an organism, the method comprising administering to the organism a RNA molecule comprising:
>
> a) a 5′-cap structure;

b) an open reading frame encoding a coronavirus antigen; and

c) a heterologous 3′-untranslated region comprising a first and a second poly(A) sequence, wherein:

(i) the first poly(A) sequence comprises at least 20 adenine nucleotides; and

(ii) the second poly(A) sequence comprises at least 70 adenine nucleotides,

wherein the first and the second poly(A) sequences are separated by a nucleic acid sequence comprising 10 nucleotides and having no more than 2 consecutive adenine nucleotides,

wherein the RNA molecule is administered intramuscularly;

wherein when the RNA molecule is expressed in the organism, the RNA molecule yields increased expression of the antigen encoded by the open reading frame in comparison to a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking the second poly(A) sequence;

wherein the RNA molecule comprises at least one nucleotide analog comprising a modified form of uridine chemically altered by methylation; and

wherein the RNA molecule is transfected into cells of the organism in a nanoparticle.

ANSWER: BioNTech and Pfizer admit that claim 23 of the ’920 patent includes the above language but deny that any of the 28 issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 111.

112. Dependent claims 24–26 narrow claim 23:

24. The method of claim 23, wherein the open reading frame has a guanidine/cytosine content that is increased by at least 15% relative to a corresponding reference open reading frame.

25. The method of claim 23, wherein the RNA molecule yields an increased immune response in comparison to an intramuscular injection of a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking the second poly(A) sequence.

26. The method of claim 25, wherein when administered intramuscularly, the RNA molecule yields an increased neutralizing antibody response in comparison to an intramuscular injection of a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking the second poly(A) sequence.

ANSWER: BioNTech and Pfizer admit that claims 24-26 of the '920 patent include the above language and deny any remaining allegations of paragraph 112.

113. Comirnaty® contains mRNA molecules (tozinameran, famtozinameran, and raxtozinameran) that contain an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen. Exhibit 16 (WHO INN Programme Report No. 11889) at 2 ("Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein"); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . .").

ANSWER: Paragraph 113 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 113 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 113.

114. The use of Comirnaty® as instructed in its package inserts is a method for treating or preventing an infectious disease, involving administering the tozinameran, tozinameran and famtozinameran, and/or raxtozinameran, each of which contain an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen, which is from the pathogen SARS-CoV-2 virus associated with the infectious disease COVID-19; and each of which contain a 3'-untranslated region containing at least two poly(A) sequences, one of which contains 70 adenine nucleotides, and in which the two poly(A) sequences are separated by 10 nucleotides; and are administered intramuscularly. For example, Section 2.2 of the Comirnaty® package insert instructs users to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly" (Exhibit 15 (Comirnaty® package insert) at 5), Section 11 states "[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein SARS-CoV-2" (*id*. at 14), and Section 12 states "[t]he nucleoside-modified

mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." *Id.* at 15; *see also* Exhibit 17 (Comirnaty® Bivalent package insert) at 17 ("COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use"). Section 12 also states that "[t]he vaccine elicits an immune response to the S antigen, which protects against COVID-19," which constitutes a method for treating or preventing an infectious disease. Exhibit 15 (Comirnaty® package insert) at 15; *see also* Exhibit 17 (Comirnaty® Bivalent package insert) at 17.

ANSWER: Paragraph 114 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 114 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 114.

115. Comirnaty® contains tozinameran, famtozinameran, and/or raxtozinameran, each of which is an mRNA molecule that contains a "cap" at the 5′ end of the molecule. Exhibit 16 (WHO INN Programme Report No. 11889) at 1 ("A modified 5'-cap1 structure (m7G+m3'-5'-ppp-5'-Am)"); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 ("Sequence length: 4269, which includes 'Cap-' to denote the presence of the 5'-cap analog").

ANSWER: Paragraph 115 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 115 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure

[Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 115.

116. Comirnaty® contains tozinameran, famtozinameran, and/or raxtozinameran, each of which is an mRNA molecule that contains a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 16 (WHO INN Programme Report No. 11889) at 1–2; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)."). The sequence of the 10-nucleotide linker is "GCAΨAΨGACΨ." Exhibit 16 (WHO INN Programme Report No. 11889) at 4 (nucleotides 4188 to 4197); Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 (nucleotides 4205 to 4214)").

ANSWER: Paragraph 116 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 116 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 116.

117. On information and belief, when the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 16 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

ANSWER: Paragraph 117 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 117 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary

Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 117.

118. On information and belief, when Comirnaty® is administered to an organism, the antigen produced by tozinameran, famtozinameran, and raxtozinameran (*i.e.*, a coronavirus spike protein) is produced at a higher level than it would be if Comirnaty® contained tozinameran, famtozinameran, and raxtozinameran lacking the second poly(A).

ANSWER: Paragraph 118 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 118 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer deny any remaining allegations of paragraph 118.

119. On information and belief, the mRNAs in Comirnaty® are complexed with lipid nanoparticles containing ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), which is also known as "ALC-0315." Exhibit 15 (Comirnaty® package insert) at 15; Exhibit 17 (Comirnaty® Bivalent package insert) at 36. ALC-0315 is a cationic lipid. Exhibit 26 (Rapporteur Review) at 188 ("The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine and two ester moieties").

ANSWER: Paragraph 119 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 119 and deny that any version of Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document

that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 119.

120. On information and belief, when Comirnaty® is administered intramuscularly to an organism, the antigen produced by tozinameran, famtozinameran, and raxtozinameran (*i.e.*, a coronavirus spike protein) elicits an immune response that is higher compared to the immune response that would be produced by the intramuscular administration of Comirnaty® containing a form of tozinameran, famtozinameran, and raxtozinameran that lacks the second poly(A). On information and belief, when Comirnaty® containing tozinameran is administered intramuscularly to an organism, the amount of neutralizing antibodies produced by tozinameran, famtozinameran, and/or raxtozinameran (*i.e.*, a coronavirus spike protein) is increased compared to the amount of neutralizing antibodies that would result from the intramuscular administration of Comirnaty® containing a form of tozinameran, famtozinameran, and/or raxtozinameran that lacks the second poly(A).

ANSWER: Paragraph 120 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 120 and deny that any version of Comirnaty® infringes any claim of the '920 patent.

121. On information and belief, the coding sequences of tozinameran, famtozinameran, and raxtozinameran have a G/C content that is increased by at least 15 percentage points compared to their original coding sequence for the spike glycoprotein on SARS-CoV-2.

ANSWER: Paragraph 121 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 121 and deny that any version of Comirnaty® infringes any claim of the '920 patent.

122. On information and belief, BioNTech Manufacturing is the holder of the FDA's Emergency Use Authorization for Comirnaty®. Exhibit 23 (FDA Approval Letter) at 1. Use of Comirnaty® as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claims 23–36 of the '920 patent. The Comirnaty® package insert instructs medical professionals to administer Comirnaty® via an intramuscular injection. Exhibit 15 (Comirnaty® package insert) at 2; Exhibit 17 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 23–36 of the '920 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that directly infringes the '920 patent. Indeed, the only use of Comirnaty® instructed in its package inserts infringes the claims of the '920 patent. Counterclaim

Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '920 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 122.

123. Prior to approval of the BLA, the use of Comirnaty® pursuant to all of Counterclaim Defendants' Emergency Use Authorizations infringed the claims of the '920 patent for the same reasons. For example, Counterclaim Defendants published a "Fact Sheet" that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Comirnaty® "has been shown to prevent COVID-19." Exhibit 24 (Fact Sheet) at 4. Booster doses can comprise the administration of a vaccine identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing (available in archival form at https://perma.cc/94KH-8R2B). Booster doses can also comprise a mixture of 15 micrograms of tozinameran and 15 micrograms of famtozinameran (*i.e.*, Comirnaty® (tozinameran and famtozinameran)) formulated in the same manner as other doses of Comirnaty® (tozinameran). *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE). On information and belief, upon approval, the product label and formulation of Comirnaty® (raxtozinameran) will be identical to Comirnaty® (tozinameran) and Comirnaty® (tozinameran and famtozinameran).

ANSWER: BioNTech and Pfizer deny the allegations of the first sentence of paragraph 123. BioNTech and Pfizer admit that Exhibit 24 to CureVac's counterclaim is a document that purports to be a "Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use in Individuals 12 Years of Age and Older" bearing a revision date of July 8, 2022, which speaks for itself. BioNTech and Pfizer admit that Pfizer maintains a website https://www.pfizer.com, which speaks for itself. BioNTech and Pfizer deny any remaining allegations in Paragraph 123.

124. On information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '920 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 23–36 of the '920 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its package inserts and/or Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '920 patent in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 124.

125. On information and belief, Counterclaim Defendants have knowledge of the '920 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '920 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 125.

126. BioNTech was aware of the applications that led to the '920 patent. On June 26, 2018, BioNTech filed an Information Disclosure Statement in U.S. Patent App. No. 15/217,555, a patent application titled "Modification of RNA, Producing an Increased Transcript Stability and Translation Efficiency," that listed the '391 publication, which is the publication of a related application that led to the '920 patent. Exhibit 25 (BioNTech IDS) at 4. ("2016/091391 WO A1 2016-06-16 Curevac AG"). Also on June 26, 2018, BioNTech provided a copy of the '391 publication to the U.S. Patent & Trademark Office. Despite their knowledge of CureVac's '391 publication, Counterclaim Defendants chose to utilize a poly(A) sequence that contains 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. On information and belief, Counterclaim Defendants knew that choosing that poly(A) design would infringe claims that issue from the '391 publication and related applications. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the application that led to the issuance of the '920 patent. D.I. 47 at 12. Counterclaim Defendants' infringement of the '920 patent has been willful.

ANSWER: Paragraph 126 appears to include language from the '920 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 126 and deny that Comirnaty® infringes any claim of the '920 patent. BioNTech and Pfizer admit that Exhibit 25 to CureVac's counterclaims is a document that purports to be "INFORMATION DISCLOSURE STATEMENT BY APPLICANT," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 126.

127. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '920 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '920 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 127.

128. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '920 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 128.

129. Counterclaim Defendants' conduct with respect to the '920 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 129.

COUNT VI – INFRINGEMENT OF THE '070 PATENT

130. CureVac incorporates each of the above paragraphs 1–129 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

131. The '070 patent is directed to methods for producing and purifying RNA to prepare pharmaceutical-grade RNA on a commercial scale. The '070 patent describes methods including the steps of providing DNA encoding the RNA, transcribing the DNA to produce RNA, and purifying the transcribed RNA by one or more steps of tangential flow filtration.

ANSWER: Paragraph 131 appears to include language from the '070 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 131 and deny that any version of Comirnaty® infringes any claim of the '070 patent.

132. The '070 patent issued with 24 claims. Independent claim 1 recites:

1. A method for producing and purifying a RNA, comprising the steps of

A) providing a plasmid DNA encoding the RNA by

A1) linearizing the plasmid DNA in a linearization reaction;

A2) optionally terminating the linearization reaction; and

A3) diafiltering and/or concentrating and/or purifying the linearization reaction comprising linearized plasmid DNA by one or more steps of tangential flow filtration TFF) using a TFF membrane cassette;

B) transcribing the linearized DNA to yield a solution comprising a transcribed RNA; and

C) diafiltering and/or concentrating and/or purifying the solution comprising the transcribed RNA by one or more steps of TFF, optionally a TFF membrane cassette.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '070 patent includes the above language but deny that any of the 24 issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 132.

133. Dependent claims 2 and 3 serially narrow claim 1:

2. The method according to claim 1, wherein step C) comprises at least one diafiltration step using TFF and/or at least one concentration step using TFF.

3. The method according to claim 2, wherein the at least one diafiltration step using TFF in step C) comprises diafiltration with an aqueous salt solution.

ANSWER: BioNTech and Pfizer admit that claims 2 and 3 of the '070 patent include the above language but deny any remaining allegations of paragraph 133.

134. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured by a method that includes linearizing the circular plasmid DNAs that encode the tozinameran and famtozinameran mRNAs, followed by ultrafiltration/diafiltration with TFF using a TFF membrane cassette. Exhibit 26 (Rapporteur Review) at 28–29 ("Linear DNA Template Manufacturing: . . . Following fermentation, the cells are harvested and chemically lysed to recover the plasmid DNA. After this lysis step, the circular plasmid DNA is purified by ultrafiltration/diafiltration and chromatography. Following purification, the circular plasmid DNA is incubated with a restriction enzyme, Eam1104I or equivalent, in order to linearize the plasmid followed by ultrafiltration/diafiltration"); Exhibit 27 (Equipment Annex) at 1, Table 1 ("UFDF Purification | Millipore Cogent ultrafiltration system . . .• Sartocube ECO membrane (stabilized cellulose) • Millipore cassette holder (SS)").

ANSWER: Paragraph 134 appears to include language from the '070 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 134 and deny that any version of

Comirnaty® infringes any claim of the '070 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer admit that Exhibit 27 to CureVac's counterclaims is a document that purports to be "Table 1 | BNT162b2 Manufacturing Equipment and Scale," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 134.

135. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured by a method that further includes the step of transcribing the linearized DNA to produce a solution that contains the transcribed RNA (either tozinameran or famtozinameran). Exhibit 26 (Rapporteur Review) at 15 ("The RNA is first synthesized via an in vitro transcription (IVT) followed by DNase I and proteinase K digestion steps, which aid in purification"); *id*. ("The primary objective of the IVT step is to synthesize RNA for drug substance production"). The transcribed RNA is purified using TFF. Exhibit 28 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)"); Exhibit 26 (Rapporteur Review) at 15 ("The crude RNA is then purified through a 2-stage ultrafiltration/diafiltration (UFDF)").

ANSWER: Paragraph 135 appears to include language from the '070 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 135 and deny that any version of Comirnaty® infringes any claim of the '070 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer admit that Exhibit 28 to CureVac's counterclaims is a document that purports to be "ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 135.

136. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured by a method that includes diafiltration of the transcribed RNA using an aqueous salt solution. Exhibit 26 (Rapporteur Review) at 17 ("To prepare for the UFDF step, the sanitized UFDF membranes are equilibrated with diafiltration 1 buffer (200 mM ammonium sulfate, 10 mM HEPES, 0.1 mM EDTA, pH 7.0) . . . Prior to UFDF, the post-proteinase K pool is diluted 2-fold with an ammonium sulfate dilution buffer (400 mM ammonium sulfate, 10 mM HEPES, 0.1 mM EDTA, pH 7.0). The diluted proteinase K pool then undergoes a 2-stage diafiltration; first with a minimum of 5 diavolumes (DV) using diafiltration 1 buffer followed by a minimum of 10 diavolumes using formulation buffer (10 mM HEPES,0.1 mM EDTA, pH 7.0)").

ANSWER: Paragraph 136 appears to include language from the '070 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 136 and deny that any version of Comirnaty® infringes any claim of the '070 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 136.

137. Thus, on information and belief, the method Counterclaim Defendants use to manufacture the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® satisfies all of the limitations of at least claims 1–3 of the '070 patent for all of the reasons described above.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 137.

138. Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1–3 of the '070 patent, either literally or under the doctrine of equivalents, by manufacturing the RNA in Comirnaty® in the United States, in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 138.

139. On information and belief, Counterclaim Defendants have infringed or will infringe at least claims 1–3 of the '070 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(g), by importing tozinameran and/or famtozinameran manufactured outside of the United States.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 139.

140. Counterclaim Defendants' infringement of the '070 patent has been willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it is manufactured using the steps recited in the claims of the '070 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 140.

141. Counterclaim Defendants continue to use the inventions claimed in the '070 patent in deliberate disregard for CureVac's patent rights.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 141.

142. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '070 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Counterclaim Defendants' infringement of the '070 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 142.

143. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '070 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 143.

144. Counterclaim Defendants' conduct with respect to the '070 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 144.

COUNT VII – INFRINGEMENT OF THE '910 PATENT

145. CureVac incorporates each of the above paragraphs 1–144 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

146. The '910 patent is directed to methods for producing and purifying RNA to prepare pharmaceutical-grade RNA on a commercial scale. The '910 patent describes methods including the steps of providing DNA encoding the RNA, transcribing the DNA to produce RNA, and purifying the transcribed RNA by one or more steps of tangential flow filtration.

ANSWER: Paragraph 146 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of Paragraph 146 and deny that any version of Comirnaty® infringes any claim of the '910 patent.

147. The '910 patent issued with 26 claims. Independent claim 1 recites:

1. A method for producing purified RNA, comprising the steps of:

A1) providing plasmid DNA encoding a RNA of 500 to 10000 nucleotides in length;

A2) linearizing the DNA with a restriction endonuclease to produce linearized DNA;

B) transcribing the linearized DNA to yield transcribed RNA, wherein said transcribing is in a solution comprising: nucleoside triphosphates (NTPs); T7 polymerase, spermidine, salts and a HEPES or TRIS buffer; and

C) purifying the transcribed RNA by performing at least one step of tangential flow filtration (TFF) using a TFF membrane cassette, thereby producing purified RNA, wherein the method comprises at least one step of DNA or RNA purification using chromatography.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '910 patent includes the above language but deny that any of the issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 147.

148. Dependent claims 6, 7, 9, 12, 13, and 18 serially narrow claim 1:

6. The method of claim 1, wherein the TFF membrane cassette comprises a cellulose-based TFF membrane.

7. The method of claim 6, wherein C) purifying the transcribed RNA comprises performing at least one step of TFF with an aqueous salt solution.

9. The method of claim 7, wherein performing at least one step of TFF comprises using a TFF membrane with a molecular weight cutoff of ≤500 kDa.

12. The method of claim 9, wherein the transcribing is in a buffer comprising 0.1 mM to 10 mM spermidine.

13. The method of claim 12, wherein the method produces purified RNA with a reduced level of spermidine relative to the level of spermidine in step B.

ANSWER: BioNTech and Pfizer admit that claims 6, 7, 9, 12, and 13 of the '910 patent include the above language but deny any remaining allegations of paragraph 148.

149. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured using a plasmid DNA approximately 7,800 nucleotides in length. Exhibit 26 (Rapporteur Review) at 23 ("The plasmid, pST4-1525, is a 7,824 base pair plasmid designed for the production of BNT162b2.").

ANSWER: Paragraph 149 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 149 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 149.

150. On information and belief, the circular plasmid DNAs that encode the tozinameran, famtozinameran, and raxtozinameran mRNAs are purified using anion exchange chromatography. Exhibit 26 (Rapporteur Review) at 31 ("pST4-1525 is manufactured by a fed-batch fermentation process initiated from the bacterial working cell bank (WCB). Following fermentation, the cells are harvested and chemically lysed to recover the plasmid DNA. After this lysis step, the circular plasmid DNA is purified by ultrafiltration/diafiltration and anion exchange chromatography.").

ANSWER: Paragraph 150 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 150 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 150.

151. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured by a method that includes linearizing the circular plasmid DNAs that encode the tozinameran and famtozinameran mRNAs. Exhibit 26 (Rapporteur Review) at 28–29 ("Linear DNA Template Manufacturing: . . . Following fermentation, the cells are harvested and chemically lysed to recover the plasmid DNA. After this lysis step, the circular plasmid DNA is purified by ultrafiltration/diafiltration and chromatography. Following purification, the circular plasmid DNA is incubated with a restriction enzyme, Eam1104I or equivalent, in order to linearize the plasmid followed by ultrafiltration/diafiltration").

ANSWER: Paragraph 151 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 151 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 151.

152. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured by a method that further includes the step of transcribing the linearized DNA in a solution containing nucleoside triphosphates, T7 polymerase, spermidine, salts, and a HEPES buffer to produce a solution that contains the transcribed RNA (either tozinameran or famtozinameran). Exhibit 26 (Rapporteur Review) at 15 ("To begin the IVT step, individual components are thawed and added to the reaction vessel, including ATP solution (100 mM adenosine 5′-triphosphate), CTP solution (100 mM cytidine 5′-triphosphate), N1-methylpseudo UTP solution (100 mM N1-methylpseudouridine 5′-triphosphate), GTP solution (100 mM guanosine 5′-triphosphate), 5′-cap solution (100 mM 5′-cap). RNase inhibitor, 10X transcription buffer (400 mM HEPES, 400 mM magnesium acetate, 100 mM DTT, 20 mM spermidine, pH 8.3) and the linear DNA template are also added to the reaction vessel with water for injection (WFI).").

ANSWER: Paragraph 152 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 152 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 152.

153. On information and belief, the transcribed tozinameran, famtozinameran, and raxtozinameran RNAs in Comirnaty® are purified using TFF in which a cellulose-based TFF membrane cassette having a 300 kDa molecular weight cutoff is utilized. Exhibit 28 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)"); Exhibit 27 (Equipment Annex) at 1, Table 1 ("UFDF Purification | Millipore

Cogent ultrafiltration system • 2x3. 5m2 (7m2) 300kD membrane • Sartocube ECO membrane (stabilized cellulose) • Millipore cassette holder (SS)").

ANSWER: Paragraph 153 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 153 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 27 to CureVac's counterclaims is a document that purports to be "Table 1 | BNT162b2 Manufacturing Equipment and Scale," which speaks for itself. BioNTech and Pfizer admit that Exhibit 28 to CureVac's counterclaims is a document that purports to be "ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 153.

154. On information and belief, the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are manufactured by a method that includes diafiltration of the transcribed RNA using an aqueous salt solution. Exhibit 26 (Rapporteur Review) at 17 ("To prepare for the UFDF step, the sanitized UFDF membranes are equilibrated with diafiltration 1 buffer (200 mM ammonium sulfate, 10 mM HEPES, 0.1 mM EDTA, pH 7.0) . . . Prior to UFDF, the post-proteinase K pool is diluted 2-fold with an ammonium sulfate dilution buffer (400 mM ammonium sulfate, 10 mM HEPES, 0.1 mM EDTA, pH 7.0). The diluted proteinase K pool then undergoes a 2-stage diafiltration; first with a minimum of 5 diavolumes (DV) using diafiltration 1 buffer followed by a minimum of 10 diavolumes using formulation buffer (10 mM HEPES,0.1 mM EDTA, pH 7.0)").

ANSWER: Paragraph 154 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 154 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical

assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 154.

155. On information and belief, the transcription reaction to produce the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® use a "10X transcription buffer" containing 20 mM spermidine, such that the concentration of spermidine in the reaction mixture is about 2 mM. Exhibit 26 (Rapporteur Review) at 15 ("To begin the IVT step, individual components are thawed and added to the reaction vessel, including . . . 10X transcription buffer (400 mM HEPES, 400 mM magnesium acetate, 100 mM DTT, 20 mM spermidine, pH 8.3) and the linear DNA template are also added to the reaction vessel with water for injection (WFI).").

ANSWER: Paragraph 155 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 155 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 155.

156. On information and belief, the TFF used to purify the products of the transcription reactions used to manufacture the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® produces tozinameran and/or famtozinameran with a reduced level of spermidine relative to the level of spermidine in the transcription reaction. Exhibit 29 (S.2.2 Description of Mfg Process and Process Controls) at 33 ("Process 1 utilizes a magnetic bead purification step for removal of small molecule impurities (e.g. spermidine, DTT), residual DNA, and enzyme impurities (e.g. T7 polymerase, DNase I). As this step was not scalable, Process 2 includes a proteinase K digestion step to reduce the size of the enzyme impurities, followed by an ultrafiltration/diafiltration purification step to remove the small molecule impurities, residual DNA, and the enzyme impurity fragments.").

ANSWER: Paragraph 156 appears to include language from the '910 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 156 and deny that any version of Comirnaty® infringes any claim of the '910 patent. BioNTech and Pfizer admit that Exhibit 29 to CureVac's counterclaims is a document that purports to be "Table of Contents S.2.2 Description

of Mfg Process and Process Controls (modRNA) [BNT Mainz and Rentschler]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 156.

157. Thus, on information and belief, the method Counterclaim Defendants use to manufacture the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® satisfies all of the limitations of at least claims 1, 6, 7, 9, 12, and 13 of the '910 patent for all of the reasons described above.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 157.

158. Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 6, 7, 9, 12, and 13 of the '910 patent, either literally or under the doctrine of equivalents, by manufacturing the RNA in Comirnaty® in the United States, in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 158.

159. On information and belief, Counterclaim Defendants have infringed or will infringe at least claims 1, 6, 7, 9, 12, and 13 of the '910 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(g), by importing tozinameran and/or famtozinameran manufactured outside of the United States.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 159.

160. Counterclaim Defendants' infringement of the '910 patent has been willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it is manufactured using the steps recited in the claims of the '910 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 160.

161. Counterclaim Defendants continue to use the inventions claimed in the '910 patent in deliberate disregard for CureVac's patent rights.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 161.

162. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '910 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Counterclaim Defendants' infringement of the '910 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 162.

163. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '910 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 163.

164. Counterclaim Defendants' conduct with respect to the '910 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 164.

COUNT VIII – INFRINGEMENT OF THE '493 PATENT

165. CureVac incorporates each of the above paragraphs 1–164 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

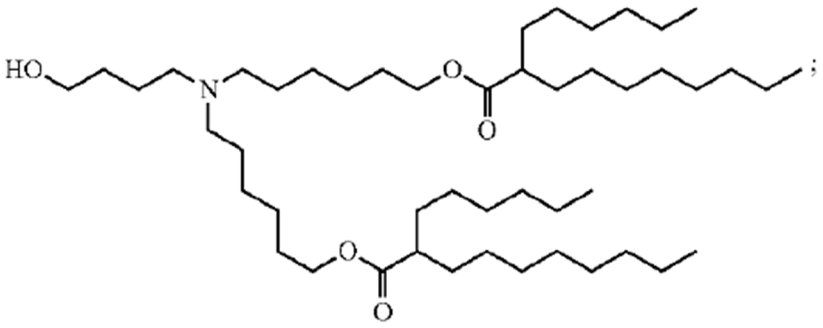
166. The '493 patent is directed to an RNA-based vaccine composition for treating coronavirus infections, in particular SARS-CoV-2 infections, that contains an mRNA that encodes a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus. The '493 patent also describes formulating the mRNA in a lipid nanoparticle ("LNP") containing at least one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polymer-conjugated lipid, preferably a polyethylene glycol-lipid ("PEG-lipid").

ANSWER: Paragraph 166 appears to include language from the '493 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 166.

167. The '493 patent issued with 27 claims. Independent claim 1 recites:

> **1.** A composition comprising a mRNA comprising:
>
> (a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO:10 that is a pre-fusion stabilized spike protein (S_stab) comprising a pre-fusion stabilizing K986P and V987P mutation;
>
> (b) at least one heterologous untranslated region (UTR); and
>
> (c) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:
>
> (i) at least one cationic lipid according to formula III-3:

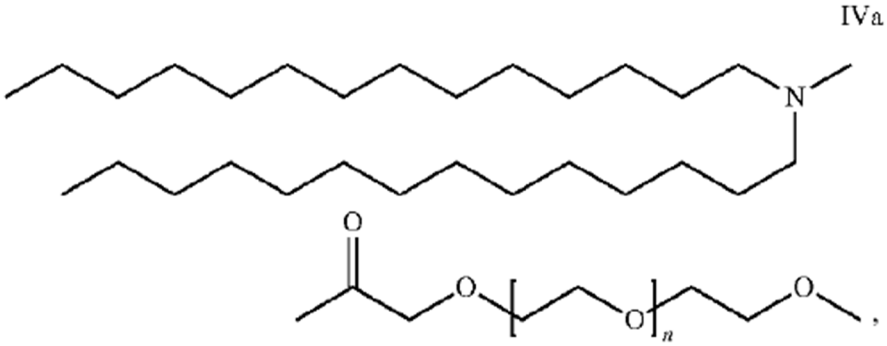
(III-3)



(ii) at least one neutral lipid, comprising 1,2-distearoylsn-glycero-3-phosphocholine (DSPC);

(iii)at least one steroid, comprising cholesterol; and (iv) at least one PEG-lipid according to formula IVa:

IVa



wherein n has a mean value ranging from 30 to 60,

wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-15% PEG-lipid.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '493 patent includes the above language but deny that any of the 27 issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 167.

168. Claims 11, 13, 18, and 22 further narrow claim 1:

11. The composition of claim 1, wherein the mRNA comprises a nucleotide analog.

13. The composition of claim 1, wherein the mRNA is a purified mRNA that has been purified by RP-HPLC and/or TFF.

18. The composition of claim 11, wherein the mRNA comprises a 1-methylpseudouridine substitution.

22. The composition of claim 1, wherein the LNP comprises a molar ratio of approximately 47.4:10:40.9:1.7 of cationic lipid:DSPC:cholesterol:PEG.

ANSWER: BioNTech and Pfizer admit that claims 11, 13, 18, and 22 of the '493 patent include the above language but deny any remaining allegations of paragraph 168.

169. On information and belief, Comirnaty® is a pharmaceutical composition containing an mRNA (*i.e.*, tozinameran, famtozinameran, and/or raxtozinameran) containing an open reading frame encoding a SARS CoV-2 viral spike protein antigen that is at least 95% identical to SEQ ID NO:10 in the '493 patent, which is a pre-fusion stabilized spike protein (S_stab) containing pre-fusion stabilizing K986P and V987P mutations. Exhibit 16 (WHO INN Programme Report No. 11889) at 1–2 ("S glycoprotein sequence containing mutations K986P and V987P," which is a "[c]odon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein containing mutations K986P and V987P to ensure the S glycoprotein remains in an antigenically optimal pre-fusion conformation," located at nucleotide positions 103-3879). On information and belief, the mRNA in Comirnaty® contains at least one heterologous untranslated region, the 5′-untranslated region derived from human alpha-globin RNA with an optimized Kozak sequence. *Id*. at 1.

ANSWER: Paragraph 169 appears to include language from the '493 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 169 and deny that any version of Comirnaty® infringes any claim of the '493 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 169.

170. On information and belief, each 0.3 milliliter dose of Comirnaty® contains either tozinameran, a combination of tozinameran and famtozinameran, or raxtozinameran complexed with the following lipid nanoparticle components: (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) at a concentration of 7.17 mg/mL, which is the compound of formula III-3 recited in claim 1 and is also known as "ALC-0315"; (ii) 1,2-distearoylsn-glycero-3-phosphocholine at a concentration of 1.56 mg/mL, which is a neutral lipid; (iii) cholesterol at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, at a concentration of 0.89 mg/mL, which is a pegylated lipid of formula IVa recited in claim 1 and is also known as "ALC-0159." Exhibit 26 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a

molar ratio of cationic lipid:DSPC:cholesterol:PEG-lipid of approximately 47.4:10:40.9:1.7. *Id.* at 116 ("In vivo experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

ANSWER: Paragraph 170 appears to include language from the '493 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 170 and deny that any version of Comirnaty® infringes any claim of the '493 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 170.

171. On information and belief, when the tozinameran, famtozinameran, and raxtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 16 (WHO INN Programme Report No. 11889) at 2–5; Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3. In other words, tozinameran, famtozinameran, and raxtozinameran contain an mRNA having a 1-methylpseudouridine substitution.

ANSWER: Paragraph 171 appears to include language from the '493 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 171 and deny that any version of Comirnaty® infringes any claim of the '493 patent. BioNTech and Pfizer admit that Exhibit 16 to CureVac's counterclaims is a document that purports to be "WHO International Nonproprietary Names Programme," which speaks for itself. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 171.

172. On information and belief, tozinameran, famtozinameran, and raxtozinameran are transcribed from their linear DNA plasmids using an in vitro transcription (IVT) step followed by purification using tangential flow filtration ("TFF"). Exhibit 28 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)").

ANSWER: Paragraph 172 appears to include language from the '493 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 172 and deny that any version of Comirnaty® infringes any claim of the '493 patent. BioNTech and Pfizer admit that Exhibit 28 to CureVac's counterclaims is a document that purports to be "ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 172.

173. The package inserts for Comirnaty® instruct a health care provider to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly." Exhibit 15 (Comirnaty® package insert) at 5; *see also* Exhibit 17 (Comirnaty® Bivalent package insert) at 7 ("After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately").

ANSWER: BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 173.

174. Thus, on information and belief, Comirnaty® satisfies all of the limitations of at least claims 1, 11, 13, 18, and 22 of the '493 patent for all of the reasons described above.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 174.

175. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally

or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Comirnaty® in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 175.

176. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to use Comirnaty® in the United States and in this District in a manner that would directly infringe the '493 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '493 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 176.

177. On information and belief, Comirnaty® constitutes a material part of the invention of at least claims 1, 11, 13, 18, and 22 of the '493 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of equivalents, by promoting the use of Comirnaty® in accordance with its approved package inserts and/or Emergency Use Authorizations in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '493 patent, in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 177.

178. On information and belief, Counterclaim Defendants supply tozinameran and/or famtozinameran manufactured in the United States for formulation into Comirnaty® outside of the United States. On information and belief, Counterclaim Defendants have infringed or will infringe at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), by supplying the global market for Comirnaty® with tozinameran and/or famtozinameran manufactured in the United States which constitutes a material part of the invention of at least claims 1, 11, 13, 18, and 22 of the '493 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

ANSWER: Paragraph 178 sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 178.

179. In July 2015, CureVac entered into a technology evaluation agreement with Acuitas Therapeutics Inc. ("Acuitas") under which CureVac evaluated certain lipid nanoparticle formulations to test their suitability as an mRNA delivery system. As part of CureVac's evaluation, CureVac conducted extensive studies regarding the safety and efficacy of various lipid

nanoparticle formulations. As a result of those studies CureVac identified a single lipid nanoparticle candidate and conducted the first human clinical trial using an mRNA formulated in a lipid nanoparticle to study a rabies vaccine candidate. On January 7, 2020, CureVac issued a press release reporting that a vaccine containing the rabies mRNA formulated in a lipid nanoparticle "induced immune response in all subjects and was well tolerated." Exhibit 30 (CureVac Press Release) at Abstract. CureVac did not disclose the specific formulation used in that first-of-its-kind human rabies vaccine trial, or the results of CureVac's extensive development efforts that led to the selection of the lipid nanoparticle formulation used in that human trial. The lipid nanoparticle used in CureVac's human rabies vaccine trial is the same lipid nanoparticle recited in the '493 patent claims.

ANSWER: BioNTech and Pfizer admit that Exhibit 30 to CureVac's counterclaims is a document that purports to be a January 7, 2020 press release titled "CureVac Announces Positive Results in Low Dose – 1 µg – Rabies Vaccine Clinical Phase 1 Study," which speaks for itself. BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 179 and therefore deny them.

180. On information and belief, in 2017, Counterclaim Defendant BioNTech entered into a collaboration with Acuitas Therapeutics Inc. ("Acuitas") related to lipid nanoparticle technologies. Exhibit 31 (Acuitas Complaint) at ¶ 30. On information and belief, in January 2020, based on its knowledge of CureVac's unpublished confidential data establishing the safety and efficacy of an mRNA vaccine formulated with the specific lipid nanoparticle recited in the '493 patent claims in humans, Acuitas recommended to BioNTech that it use that same lipid nanoparticle CureVac used in its human rabies vaccine trial (and that is recited in the '493 patent claims) in formulating its COVID-19 vaccine. *Id*. On information and belief, prior to Acuitas's disclosure to BioNTech of CureVac's confidential proprietary results with the lipid nanoparticle recited in the '493 patent claims, Counterclaim Defendants' COVID-19 vaccine development program was utilizing a different lipid nanoparticle. Because Counterclaim Defendants received CureVac's confidential proprietary information from Acuitas regarding CureVac's success in formulating a safe and effective mRNA vaccine with the lipid nanoparticle recited in the '493 patent claims, Counterclaim Defendants copied the lipid nanoparticle formulation that CureVac showed was successful for use in Comirnaty®. Counterclaim Defendants' decision to copy the lipid nanoparticle formulation used by CureVac evinces a deliberate disregard for CureVac's patent rights. Counterclaim Defendants chose to advance BNT162b2 as their lead vaccine candidate knowing that it copied CureVac's formulation recited in the claims of the '493 patent. Counterclaim Defendants have continued to use the invention claimed in the '493 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '493 patent. D.I. 47 at 12. Accordingly, Counterclaim Defendants' infringement of the '493 patent has been willful.

ANSWER: BioNTech and Pfizer admit that BioNTech SE entered into a collaboration with Acuitas in 2017. BioNTech and Pfizer deny the remaining allegations of paragraph 180.

181. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '493 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '493 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 181.

182. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '493 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 182.

183. Counterclaim Defendants' conduct with respect to the '493 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 183.

COUNT IX – INFRINGEMENT OF THE '525 PATENT

184. CureVac incorporates each of the above paragraphs 1–183 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

185. The application that led to the issuance of the '525 patent was filed as a continuation of the same application to which the application that led to the '493 patent, and therefore the '525 patent shares a common specification with the '493 patent. The '525 patent is directed to methods of stimulating an immune response using an RNA-based vaccine composition that are directed to treating coronavirus infections, and in particular SARS-CoV-2 infections, by administering compositions that contain an mRNA that encodes a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus formulated in a lipid nanoparticle.

ANSWER: Paragraph 185 appears to include language from the '525 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 185.

186. The '525 patent issued with 29 claims. Independent claim 1 recites:

1. A method of stimulating an immune response in a subject, the method comprising administering to the subject an effective amount of a composition comprising:

(I) a mRNA comprising:

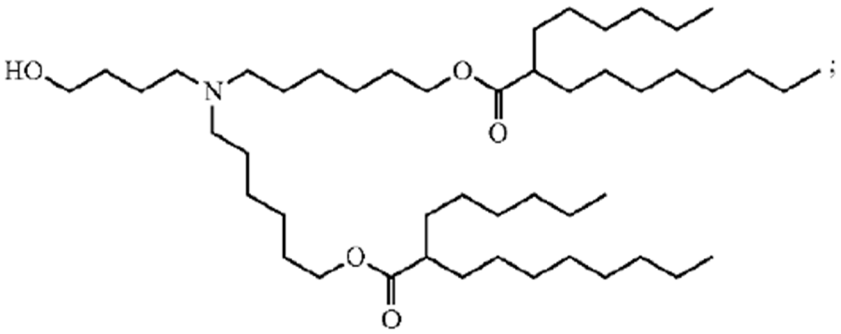
(a) at least one coding sequence which is at least 80% identical to SEQ ID NO: 137 encoding a severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) spike protein (S) at least 90% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising a pre-fusion stabilizing K986P and V987P mutation and comprising a D614G amino acid substitution; and

(b) a 5′ heterologous untranslated region (UTR) and a heterologous 3′ UTR, said heterologous 3′ UTR comprising a terminal poly(A) sequence of 30 to 200 adenosine nucleotides; and

(II) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed with lipid nanoparticles (LNP) and wherein the LNP comprise:

(i) at least one cationic lipid according to formula III-3:

(III-3)



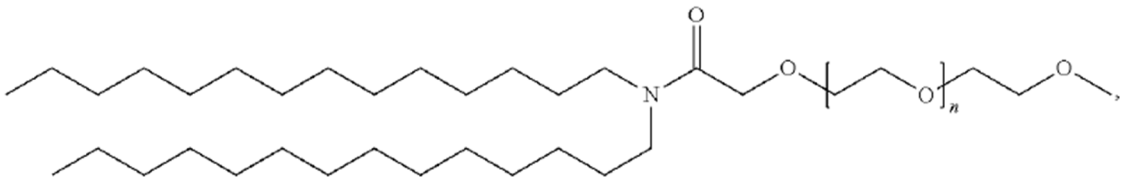
;

(ii) at least one neutral lipid, comprising 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC);

(iii) at least one steroid, comprising cholesterol; and

(iv) at least one polyethylene glycol (PEG)-lipid according to formula IVa:

IVa



wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-5% PEG-lipid,

wherein the composition is administered by intramuscular injection.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '525 patent includes the above language but deny that any of the 29 issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 186.

187. Claims 2, 3, and 13 serially narrow claim 1:

2. The method of claim 1, wherein the mRNA comprises at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10.

3. The method of claim 2, wherein the mRNA comprises a 5′-cap structure.

13. The method of claim 3, wherein the mRNA has been purified by a method comprising tangential flow filtration (TFF).

ANSWER: BioNTech and Pfizer admit that claims 2, 3, and 13 of the '525 patent include the above language but deny any remaining allegations of paragraph 187.

188. The use of Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) as instructed in their package inserts results in the stimulation of an immune response by administering famtozinameran and/or raxtozinameran mRNA molecules, each of which contain an open reading frame encoding a SARS CoV-2 viral spike protein antigen. *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE) ("Clinical data from a Phase 2/3 trial showed a booster dose of Pfizer and BioNTech's Omicron BA.1-adapted bivalent vaccine elicited a superior immune response against the Omicron BA.1 subvariant compared to the companies' current COVID-19 vaccine, with a favorable safety profile").

ANSWER: Paragraph 188 appears to include language from the '525 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 188 and deny that any version of Comirnaty® infringes any claim of the '525 patent. BioNTech and Pfizer admit that the Press Release is a document that purports to be the August 31, 2022 "Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 188.

189. On information and belief, Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) are pharmaceutical compositions containing an mRNA (*i.e.*, famtozinameran and/or raxtozinameran) having a coding sequence encoding a SARS-CoV-2 spike protein (S) antigen. Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . ."). On information and belief, famtozinameran has a coding sequence that is about 86% identical to SEQ ID NO: 137 in the '525 patent. The coding sequence of famtozinameran encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '525 patent, and contains pre-fusion stabilizing K986P and V987P mutations and a D614G amino acid substitution. *Id.* at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions (reference for numbering Genbank ID QHD43416.1): T19I, ΔLPP24-26, A27S, ΔHV69-70, G142D, V213G, G339D, S371L, S373P, S375F, T376A, D405N, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, **D614G**, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K, **KV986-987PP**") (emphasis added). On information and belief, raxtozinameran has a coding sequence that is about 85% identical to SEQ ID NO: 137 in the '525 patent. The coding sequence of raxtozinameran encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '525 patent, and contains pre-fusion stabilizing K986P and V987P mutations and a D614G amino acid substitution. Exhibit 21 (CAS Reg. No. 2887554-49-4) at 1–2.

ANSWER: Paragraph 189 appears to include language from the '525 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 189 and deny that any version of Comirnaty® infringes any claim of the '525 patent. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure

[Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 189.

190. On information and belief, the mRNAs in Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) have a 5′-cap structure, and have 5′ and 3′ heterologous untranslated regions, the latter containing a terminal poly(A) comprising 70 adenosine residues. Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("**hAg-Kozak (nucleotides 1 to 53):** 5'-UTR sequence of the human alpha-globin mRNA with an optimized 'Kozak sequence' to increase translational efficiency"); *id.* at 2 ("A cap1 structure m27,3'-OGppp(m12'-O)ApG is utilized as specific capping structure at the 5′-end of the RNA drug substance"); *id.* at 4 ("**A30L70 (nucleotides 4159 to 4268)**: The circular plasmid, described in Section 3.2.S.2.3 Control of Materials – Source, History and Generation of Plasmids BNT162b2 [Omicron (BA.4/BA.5) Variant], provides a template for an mRNA transcript that contains two poly(A) tracts of 30 and approximately 70 adenosine residues joined by a linker") (emphases in original); Exhibit 21 (CAS Reg. No. 2887554-49-4) at 1–2.

ANSWER: Paragraph 190 appears to include language from the '525 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 190 and deny that any version of Comirnaty® infringes any claim of the '525 patent. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 190.

191. On information and belief, each 0.3 milliliter dose of Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) contains either a combination of tozinameran and famtozinameran, or raxtozinameran, complexed with the following lipid nanoparticle components (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) at a concentration of 7.17 mg/mL, which is the compound of formula III-3 recited in claim 1 and is also known as "ALC-0315"; (ii) 1,2-distearoylsn-glycero-3-phosphocholine at a concentration of 1.56 mg/mL, which is a neutral lipid; (iii) cholesterol at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide,

at a concentration of 0.89 mg/mL, which is a pegylated lipid of formula IVa recited in claim 1 and is also known as "ALC-0159." Exhibit 26 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) are present in a molar ratio of cationic lipid:DSPC:cholesterol:PEG-lipid of approximately 47.5:10:40.7:1.8. *Id*. at 116 ("In vivo experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

ANSWER: Paragraph 191 appears to include language from the '525 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 191 and deny that any version of Comirnaty® infringes any claim of the '525 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 191.

192. On information and belief, the package inserts for Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) instruct a health care provider to administer a single 0.3 mL dose of Comirnaty® intramuscularly. Exhibit 17 (Comirnaty® Bivalent package insert) at 7 ("After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately"); *id.* at 46 ("Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection").

ANSWER: BioNTech and Pfizer admit that Exhibit 15 to CureVac's counterclaims is a document that purports to be the 2021 "Prescribing Information" for Comirnaty®, which speaks for itself. BioNTech and Pfizer admit that Exhibit 17 to CureVac's counterclaims is a document that purports to be "FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 192.

193. On information and belief, the famtozinameran and raxtozinameran in Comirnaty® are transcribed from a linear DNA plasmid using an in vitro transcription (IVT) step followed by purification using tangential flow filtration ("TFF"). Exhibit 28 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)").

ANSWER: Paragraph 193 appears to include language from the '525 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 192 and deny that any version of Comirnaty® infringes any claim of the '525 patent. BioNTech and Pfizer admit that Exhibit 28 to CureVac's counterclaims is a document that purports to be "ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 193.

194. On information and belief, BioNTech Manufacturing is the holder of the relevant FDA authorization for Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran). Exhibit 32 (Bivalent Letter) at 1. On information and belief, the use of Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) as instructed by their package inserts satisfies each and every element of at least claims 1–3 and 13 of the '525 patent. On information and belief, the package inserts instruct medical professionals to administer Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) via an intramuscular injection. Exhibit 17 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1–3 and 13 of the '525 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in the United States and in this District in a manner that would directly infringe the '525 patent. Indeed, the only use of Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) as instructed in its package insert infringes the claims of the '525 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '525 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer admit that Exhibit 32 of CureVac's counterclaims is a document that purports to be "Pfizer BioNTech COVID-19 Vaccine, Bivalent – New Vial Presentation Available to Provide Booster Doses for Ages 12 years and older," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 194.

195. On information and belief, Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) constitute a material part of the invention of one or more claims of the '525 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1–3 and 13 of the '525 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in accordance with their authorized uses in the United States and in this District by healthcare providers, and knowing that Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) are especially made or especially adapted for use to infringe the '525 patent in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 195.

196. On information and belief, Counterclaim Defendants had knowledge of the '525 patent and knowledge that their actions promoting the use of Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in the United States induces infringement and contributorily infringes the '525 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 196.

197. In July 2015, CureVac entered into a technology evaluation agreement with Acuitas under which CureVac evaluated certain lipid nanoparticle formulations to test their suitability as an mRNA delivery system. As part of CureVac's evaluation, CureVac conducted extensive studies regarding the safety and efficacy of various lipid nanoparticle formulations. As a result of those studies CureVac identified a single lipid nanoparticle candidate and conducted the first human clinical trial using an mRNA formulated in a lipid nanoparticle to study a rabies vaccine candidate. On January 7, 2020, CureVac issued a press released reporting that vaccine containing the rabies mRNA formulated in a lipid nanoparticle "induced immune response in all subjects and was well tolerated." Exhibit 30 (CureVac Press Release) at Abstract. CureVac did not disclose the specific formulation used in that first-of-its-kind human rabies vaccine trial, or the results of CureVac's extensive development efforts that led to the selection of the lipid nanoparticle formulation used in that human trial. The lipid nanoparticle used in CureVac's human rabies vaccine trial is the same lipid nanoparticle recited in the '525 patent claims.

ANSWER: BioNTech and Pfizer admit that Exhibit 30 to CureVac's counterclaims is a document that purports to be a January 7, 2020 press release titled "CureVac Announces Positive Results in Low Dose – 1 µg – Rabies Vaccine Clinical Phase 1 Study," which speaks for itself. BioNTech and Pfizer lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 197 and therefore deny them.

198. On information and belief, in 2017 Counterclaim Defendant BioNTech entered into a collaboration with Acuitas Therapeutics Inc. ("Acuitas") related to lipid nanoparticle technologies. Exhibit 31 (Acuitas Complaint) at ¶ 30. On information and belief, in January

2020, based on its knowledge of CureVac's unpublished confidential data establishing the safety and efficacy of an mRNA vaccine formulated with the specific lipid nanoparticle recited in the '525 patent claims in humans, Acuitas recommended to BioNTech that it use that same lipid nanoparticle CureVac used in its human rabies vaccine trial (and that is recited in the '525 patent claims) in formulating its COVID-19 vaccine. *Id*. On information and belief, prior to Acuitas's disclosure of CureVac's confidential proprietary results with the lipid nanoparticle recited in the '525 patent claims to BioNTech, Counterclaim Defendants' COVID-19 vaccine development program was utilizing a different lipid nanoparticle. Because Counterclaim Defendants received CureVac's confidential proprietary information from Acuitas regarding CureVac's success in formulating a safe and effective mRNA vaccine with the lipid nanoparticle recited in the '525 patent claims, Counterclaim Defendants copied the lipid nanoparticle formulation that was brought to the clinic by CureVac for use in Comirnaty®. Counterclaim Defendants' decision to copy CureVac's lipid nanoparticle formulation evinces a deliberate disregard for CureVac's patent rights. Counterclaim Defendants chose to advance BNT162b2 as their lead vaccine candidate knowing that it comprises the components copied from CureVac's formulation and recited in the claims of the '525 patent. Counterclaim Defendants have continued to use the invention claimed in the '525 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran and/or raxtozinameran. Moreover, by at least April 7, 2022, BioNTech was provided with a presentation identifying 37 patents and patent applications in CureVac's patent portfolio, including the application that led to the issuance of the '525 patent. D.I. 47 at 12. Accordingly, Counterclaim Defendants' infringement of the '525 patent has been willful. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '525 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '525 patent.

ANSWER: BioNTech and Pfizer admit that BioNTech SE entered into a collaboration with Acuitas in 2017. BioNTech and Pfizer deny the remaining allegations of paragraph 198.

199. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '525 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 199.

200. Counterclaim Defendants' conduct with respect to the '525 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 200.

COUNT X – INFRINGEMENT OF THE '966 PATENT

201. CureVac incorporates each of the above paragraphs 1–201 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

202. The application that led to the issuance of the '966 patent was filed as a continuation of the same application that led to the '493 and '525 patents, and therefore the '966 patent shares a common specification with the '493 and '525 patents. The '966 patent is directed to RNA-based vaccine compositions for treating coronavirus infections, in particular SARS-CoV-2 infections, containing an mRNA that encodes a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus, and has additional mutations. The '966 patent also describes formulating the mRNA in a lipid nanoparticle ("LNP") containing at least one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polymer conjugated lipid, preferably a polyethylene glycol-lipid.

ANSWER: Paragraph 202 appears to include language from the '966 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 202.

203. The '966 patent issued with 27 claims. Independent claim 1 recites:

> **1.** A composition comprising a mRNA comprising:
>
> (a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing mutations and H69del, V70del, S477N, T478K, E484A, N501Y, and D614G amino acid substitutions relative to SEQ ID NO: 10;
>
> (b) at least one heterologous untranslated region (UTR); and
>
> (c) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:
>
> (i) at least one cationic lipid;
>
> (ii) at least one neutral lipid;
>
> (iii)at least one steroid or steroid analogue; and
>
> (iv)at least one PEG-lipid,
>
> wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-10% PEG-lipid.

ANSWER: BioNTech and Pfizer admit that claim 1 of the '966 patent includes the above language but deny that any of the 27 issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 203.

204. Claims 4, 11, and 14 narrow claim 1:

> **4.** The composition of claim 1, wherein the at least one coding sequence of the mRNA has a G/C content of at least about 50%.
>
> **11.** The composition of claim 1, wherein the mRNA is a purified mRNA that has been purified by RP-HPLC and/or TFF.
>
> **14.** The composition of claim 1, wherein at least 80% of the mRNA is intact at least about two weeks after storage as a liquid at temperatures of about 5° C.

ANSWER: BioNTech and Pfizer admit that claims 4, 11, and 14 of the '966 patent include the above language but deny any remaining allegations of paragraph 204.

205. Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) contains famtozinameran, which is an mRNA molecule that contain an open reading frame (ORF) encoding a SARS CoV-2 viral spike protein antigen. Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . ."). On information and belief, famtozinameran has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '525 patent, and contains the pre-fusion stabilizing K986P and V987P mutations, and has the following amino acid substitutions relative to SEQ ID NO: 10: H69del, V70del, S477N, T478K, E484A, N501Y, and D614G. *Id*. at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions (reference for numbering Genbank ID QHD43416.1): T19I, ΔLPP24-26, A27S, **ΔHV69-70**, G142D, V213G, G339D, S371L, S373P, S375F, T376A, D405N, K417N, N440K, L452R, **S477N**, **T478K**, **E484A**, F486V, Q498R, **N501Y**, Y505H, **D614G**, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K, **KV986-987PP**") (emphasis added).

ANSWER: Paragraph 205 appears to include language from the '966 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 205 and deny that any version of Comirnaty® infringes any claim of the '966 patent. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure

[Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 205.

206. On information and belief, the mRNA in Comirnaty® (tozinameran and famtozinameran) contains at least one heterologous untranslated region: the 5′-untranslated region derived from human alpha-globin RNA with an optimized Kozak sequence. Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("**hAg-Kozak (nucleotides 1 to 53)**: 5'-UTR sequence of the human alpha-globin mRNA with an optimized 'Kozak sequence' to increase translational efficiency").

ANSWER: BioNTech and Pfizer admit that Exhibit 18 is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 206.

207. On information and belief, each 0.3 milliliter dose of Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) contains a combination of tozinameran and famtozinameran complexed with the following lipid nanoparticle components (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) at a concentration of 7.17 mg/mL, which is the compound of formula III-3 recited in claim 1 and is also known as "ALC-0315"; (ii) 1,2-distearoylsn-glycero-3-phosphocholine at a concentration of 1.56 mg/mL, which is a neutral lipid; (iii) cholesterol at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, at a concentration of 0.89 mg/mL, which is a pegylated lipid of formula IVa recited in claim 1 and is also known as "ALC-0159." Exhibit 26 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a molar ratio of cationic lipid:DSPC:cholesterol:PEG-lipid of approximately 47.5:10:40.7:1.8. *Id*. at 116 ("In vivo experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

ANSWER: Paragraph 207 appears to include language from the '966 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 207 and deny that any version of Comirnaty® infringes any claim of the '966 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 207.

208. On information and belief, the coding sequence of famtozinameran has a G/C content of about 57%. *See* Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 5–6.

ANSWER: Paragraph 208 appears to include language from the '966 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 208 and deny that any version of Comirnaty® infringes any claim of the '966 patent. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 208.

209. On information and belief, famtozinameran and raxtozinameran are transcribed from a linear DNA plasmid using an in vitro transcription (IVT) step followed by purification using tangential flow filtration ("TFF"). Exhibit 28 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)").

ANSWER: Paragraph 209 appears to include language from the '966 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 209 and deny that any version of Comirnaty® infringes any claim of the '966 patent. BioNTech and Pfizer admit that Exhibit 28 to CureVac's counterclaims is a document that purports to be "ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 209.

210. On information and belief, the famtozinameran in Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) is at least 80% intact at least about two weeks after storage as a liquid at temperatures of about 5° C. Exhibit 26 (Rapporteur Review) at 184 ("At accelerated conditions of +5°C-storage and up to 4 months testing of a clinical batch of drug product, LNP polydispersity and RNA integrity were out of specification at the 3 and 4 month-points").

ANSWER: BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical assessment report," which speaks for itself. BioNTech and Pfizer deny the remaining allegations of paragraph 210.

211. Thus, on information and belief, Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) satisfies all of the limitations of at least claims 1, 4, 11, and 14 of the '966 patent for all of the reasons described above.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 211.

212. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 4, 11, and 14 of the '966 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 212.

213. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1, 4, 11, and 14 of the '966 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to use Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) in the United States and in this District in a manner that would directly infringe the '966 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '966 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 213.

214. On information and belief, Comirnaty® (tozinameran and famtozinameran) constitutes a material part of the invention of at least claims 1, 4, 11, and 14 of the '966 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1, 4, 11, and 14 of the '966 patent, either literally or under the doctrine of equivalents, by promoting the use of Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) in accordance with their authorized uses in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® (tozinameran and famtozinameran) is especially made or especially adapted for use to infringe the '966 patent, in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 214.

215. On information and belief, Counterclaim Defendants had knowledge of the '966 patent and knowledge that their actions promoting the use of Counterclaim Defendants'

Comirnaty® (tozinameran and famtozinameran) in the United States induces infringement and contributorily infringes the '966 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 215.

216. Counterclaim Defendants have continued to use the invention claimed in the '966 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran. Moreover, by at least April 7, 2022, BioNTech was provided with a presentation identifying 37 patents and patent applications in CureVac's patent portfolio, including the application that led to the issuance of the '966 patent. D.I. 47 at 12. Accordingly, Counterclaim Defendants' infringement of the '966 patent has thus been willful.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 216.

217. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '966 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '966 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 217.

218. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '966 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 218.

219. Counterclaim Defendants' conduct with respect to the '966 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 219.

COUNT XI – INFRINGEMENT OF THE '686 PATENT

220. CureVac incorporates each of the above paragraphs 1–220 as though fully set forth herein.

ANSWER: BioNTech and Pfizer reallege and incorporate by reference all paragraphs in their Answer above as if fully set forth herein.

221. The application that led to the issuance of the '686 patent was filed as a continuation of the application that led to the '493, '525, and '966 patents, and therefore the '686 patent shares a common specification with the '493, '525, and '966 patents. The '686 patent is directed to purified mRNAs that encode a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus, as well as additional mutations. The '686 patent also describes formulating the mRNA in a lipid nanoparticle ("LNP") containing at least

one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polyethylene glycol (PEG)-lipid.

ANSWER: Paragraph 221 appears to include language from the '686 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required BioNTech and Pfizer deny the allegations of paragraph 221.

222. The '686 patent issued with 30 claims. Independent claim 26 recites:

> **26.** A composition comprising:
>
> (I) a purified mRNA comprising:
>
> (a) a 5' cap structure;
>
> (b) a heterologous 5' untranslated region (UTR);
>
> (c) a coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing substitutions and further comprising a D614G amino acid substitution relative to SEQ ID NO: 10; and
>
> (d) a heterologous 3' UTR, comprising a terminal poly(A) sequence of 30 to 200 adenosine nucleotides,
>
> wherein 100% of the uracil positions in the mRNA are replaced with 1-methylpseudouridine; and
>
> (II) at least one pharmaceutically acceptable carrier,
>
> wherein the mRNA is complexed or associated with lipid nanoparticles (LNPs).

ANSWER: BioNTech and Pfizer admit that claim 26 of the '686 patent includes the above language but deny that any of the 30 issued claims properly claims any patentable subject matter. BioNTech and Pfizer deny any remaining allegations of paragraph 222.

223. Claim 27 narrows claim 26:

> **27.** The composition of claim 26, wherein the LNPs comprises:
>
> (i) at least one cationic lipid;

(ii) at least one neutral lipid;

(iii)at least one steroid or steroid analogue; and

(iv)at least one PEG-lipid,

wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-5% PEG-lipid.

ANSWER: BioNTech and Pfizer admit that claim 27 of the '686 patent include the above language but deny any remaining allegations of paragraph 223.

224. Claim 30 is directed to a method of stimulating an immune response, and recites:

30. A method of stimulating an immune response to a coronavirus spike protein in a subject comprising administering to the subject an effective amount of a composition according to claim 27.

ANSWER: BioNTech and Pfizer admit that claim 30 of the '686 patent include the above language and deny any remaining allegations of paragraph 224.

225. Counterclaim Defendants' Comirnaty® is a pharmaceutical composition containing an mRNA (*i.e.*, tozinameran, famtozinameran, and/or raxtozinameran) having at least one coding sequence encoding the SARS CoV-2 viral spike protein antigen. Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . ."). On information and belief, famtozinameran has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '686 patent, and contains the pre-fusion stabilizing K986P and V987P mutations and the D614G amino-acid substitution relative to SEQ ID NO: 10. *Id.* at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions (reference for numbering Genbank ID QHD43416.1): . . . **D614G** . . . **KV986-987PP**") (emphasis added). On information and belief, raxtozinameran has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '686 patent, and contains the pre-fusion stabilizing K986P and V987P mutations and the D614G amino-acid substitution relative to SEQ ID NO: 10. Exhibit 21 (CAS Reg. No. 2887554-49-4) at 1–2.

ANSWER: Paragraph 225 appears to include language from the '686 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 225 and deny that any version of Comirnaty® infringes any claim of the '686 patent. BioNTech and Pfizer admit that Exhibit 18 to

CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 225.

226. On information and belief, the famtozinameran and raxtozinameran molecules in Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) contain a "cap" at the 5' end of the molecule. Exhibit 18 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 ("Sequence length: 4269, which includes 'Cap-' to denote the presence of the 5'-cap analog"); Exhibit 21 (CAS Reg. No. 2887554-49-4) at 1–2. On information and belief, the famtozinameran and raxtozinameran molecules in Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) contain at least one heterologous 5' untranslated region, the 5'-untranslated region derived from human alpha-globin RNA with an optimized Kozak sequence. *Id.* at 4 ("**hAg-Kozak (nucleotides 1 to 53):** 5'-UTR sequence of the human alpha-globin mRNA with an optimized 'Kozak sequence' to increase translational efficiency"), and at least one 3' untranslated region that contains a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. *Id.* (emphasis in original).

ANSWER: Paragraph 226 appears to include language from the '686 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 226 and deny that any version of Comirnaty® infringes any claim of the '686 patent. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 226.

227. On information and belief, when the famtozinameran and raxtozinameran mRNA molecules in Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) are transcribed from their plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 18 (Sec.

3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3; Exhibit 21 (CAS Reg. No. 2887554-49-4) at 1.

ANSWER: Paragraph 227 appears to include language from the '686 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 227 and deny that any version of Comirnaty® infringes any claim of the '686 patent. BioNTech and Pfizer admit that Exhibit 18 to CureVac's counterclaims is a document that purports to be "BNT162b2 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]," which speaks for itself. BioNTech and Pfizer admit that Exhibit 21 to CureVac's counterclaims is a document that purports to be "REGISTRY COPYRIGHT 2023 ACS on STN," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 227.

228. On information and belief, each 0.3 milliliter dose of Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) contains either a combination of tozinameran and famtozinameran, or raxtozinameran complexed with the following lipid nanoparticle components (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), which is a cationic lipid, at a concentration of 7.17 mg/mL; (ii) 1,2-distearoylsn-glycero-3-phosphocholine, which is a neutral lipid, at a concentration of 1.56 mg/mL; (iii) cholesterol, which is a steroid, at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, which is a pegylated (PEG)-lipid known as PEG-2000-DMG, at a concentration of 0.89 mg/mL. Exhibit 26 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a molar ratio of 47.5% cationic lipid, 10% DSPC, 40.7% cholesterol, and 1.8% PEG-lipid. *Id*. at 116 ("In vivo experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

ANSWER: Paragraph 228 appears to include language from the '686 patent, and to that extent sets forth legal conclusions to which no response is required. To the extent a response is required, BioNTech and Pfizer deny the allegations of paragraph 228 and deny that any version of Comirnaty® infringes any claim of the '686 patent. BioNTech and Pfizer admit that Exhibit 26 to CureVac's counterclaims is a document that purports to be "Rapporteur Rolling Review critical

assessment report," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 228.

229. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 26 and 27 of the '686 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 229.

230. On information and belief, BioNTech Manufacturing is the holder of all FDA's authorizations for Comirnaty®. Exhibit 32 (Bivalent Letter) at 1. On information and belief, use of Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claim 30 of the '686 patent: the package insert instructs medical professionals to administer Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) via an intramuscular injection, and thereby stimulate an immune response to a coronavirus spike protein. Exhibit 17 (Comirnaty® Bivalent package insert) at 2.

ANSWER: BioNTech and Pfizer admit that Exhibit 32 of CureVac's counterclaims is a document that purports to be "Pfizer BioNTech COVID-19 Vaccine, Bivalent – New Vial Presentation Available to Provide Booster Doses for Ages 12 years and older," which speaks for itself. BioNTech and Pfizer deny any remaining allegations of paragraph 230.

231. Thus, on information and belief, Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) satisfies all of the limitations of at least claims 26, 27, and 30 in the '686 patent for all of the reasons described above.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 231.

232. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 26 and 27 in the '686 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 232.

233. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claim 30 in the '686 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare

providers and patients, to use Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in the United States and in this District in a manner that would directly infringe the '686 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '686 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 233.

234. On information and belief, Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) constitute a material part of the invention of one or more claims in the '686 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claim 30 in the '686 patent, either literally or under the doctrine of equivalents, by promoting the use of Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in accordance with its FDA authorizations in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) are especially made or especially adapted for use to infringe the '686 patent, in violation of 35 U.S.C. § 271(c).

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 234.

235. On information and belief, Counterclaim Defendants had knowledge of the '686 patent and knowledge that their actions promoting the use of Counterclaim Defendants' Comirnaty® (tozinameran and famtozinameran) and Comirnaty® (raxtozinameran) in the United States induces infringement and contributorily infringes the '686 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 235.

236. Counterclaim Defendants have continued to use the invention claimed in the '686 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran and raxtozinameran. Accordingly, Counterclaim Defendants' infringement of the '686 patent has thus been willful.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 236.

237. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '686 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '686 patent.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 237.

238. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '686 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 238.

239. Counterclaim Defendants' conduct with respect to the '686 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: BioNTech and Pfizer deny the allegations of paragraph 239.

CUREVAC'S PRAYER FOR RELIEF

The "WHEREFORE" paragraphs following paragraph 239 state CureVac's Prayer for Relief, to which no response is required. To the extent a response is required, BioNTech and Pfizer deny that CureVac is entitled to any of the relief in the Prayer for Relief, or any relief whatsoever.

* * *

Any allegation in CureVac's First Amended Counterclaims not expressly admitted herein is denied.

AFFIRMATIVE DEFENSES

BioNTech and Pfizer assert the following affirmative defenses without prejudice to the denials in their Answers to CureVac's First Amended Counterclaims and without admitting any allegations of the First Amended Counterclaims not otherwise admitted. BioNTech and Pfizer do not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. BioNTech and Pfizer reserve the right to assert other defenses and/or to supplement or amend its Answers to CureVac's First Amended Counterclaims upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE
(Invalidity of the '312 Patent)

1. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

2. As set forth above, and in particular, in Counterclaim paragraphs 32, 35, 36, and 39, the claims of the '312 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§

101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

3. Without limitation, the claims of the '312 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraph 35.

4. In addition, the claims of the '312 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of the '278 Patent)

5. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

6. As set forth above, and in particular, in Counterclaim paragraphs 32, 37, and 39, the claims of the '278 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

7. Without limitation, the claims of the '278 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraph 37.

8. In addition, the claims of the '278 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of the '492 Patent)

9. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

10. As set forth above, and in particular, in Counterclaim paragraphs 32, 37, and 39, the claims of the '492 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

11. Without limitation, the claims of the '492 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraph 37.

12. In addition, the claims of the '492 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of the '920 Patent)

13. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

14. As set forth above, and in particular, in Counterclaim paragraphs 32, 37, and 39, the claims of the '920 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability

of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

15. Without limitation, the claims of the '920 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraph 37.

16. In addition, the claims of the '920 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

FIFTH AFFIRMATIVE DEFENSE
(Invalidity of the '070 Patent)

17. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

18. As set forth above, and in particular, in Counterclaim paragraphs 32, 38, and 39, the claims of the '070 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

19. Without limitation, the claims of the '070 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraphs 38.

20. In addition, the claims of the '070 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of the '910 Patent)

21. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

22. As set forth above, and in particular, in Counterclaim paragraphs 32, 38, and 39, the claims of the '910 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

23. Without limitation, the claims of the '910 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraphs 38.

24. In addition, the claims of the '910 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

SEVENTH AFFIRMATIVE DEFENSE
(Invalidity of the '493 Patent)

25. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

26. As set forth above, and in particular, in Counterclaim paragraphs 32, 33, 34, and 39, the claims of the '493 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and

enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

27. Without limitation, the claims of the '493 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraphs 33 and 34.

28. In addition, the claims of the '493 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of the '525 Patent)

29. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

30. As set forth above, and in particular, in Counterclaim paragraphs 32, 33, 34, and 39, the claims of the '525 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

31. Without limitation, the claims of the '525 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraphs 33 and 34.

32. In addition, the claims of the '525 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

NINTH AFFIRMATIVE DEFENSE
(Invalidity of the '966 Patent)

33. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

34. As set forth above, and in particular, in Counterclaim paragraphs 32, 33, 34, and 39, the claims of the '966 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

35. Without limitation, the claims of the '966 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraphs 33 and 34.

36. In addition, the claims of the '966 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of the '686 Patent)

37. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

38. As set forth above, and in particular, in Counterclaim paragraphs 32, 33, 34, and 39, the claims of the '686 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created requirements for patentability and

enforceability of patents, such as obviousness-type double patenting, and/or in view of the defenses recognized in 35 U.S.C. § 282.

39. Without limitation, the claims of the ’686 patent are anticipated and/or obvious based on prior art, including but not limited to, prior art described above in Counterclaim paragraphs 33 and 34.

40. In addition, the claims of the ’686 patent are not adequately described, defined, and/or enabled across the full scope of the claims.

ELEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of the ’312 Patent)

41. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

42. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the ’312 patent.

TWELFTH AFFIRMATIVE DEFENSE
(Noninfringement of the ’278 Patent)

43. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

44. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the ’278 patent.

THIRTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the ’492 Patent)

45. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of its Counterclaims as if fully set forth herein.

46. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the ’492 patent.

FOURTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the '920 Patent)

47. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

48. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '920 patent.

FIFTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the '070 Patent)

49. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

50. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '070 patent.

SIXTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the '910 Patent)

51. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

52. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '910 patent.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the '493 Patent)

53. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

54. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '493 patent.

EIGHTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the '525 Patent)

55. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

56. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '525 patent.

NINETEENTH AFFIRMATIVE DEFENSE
(Noninfringement of the '966 Patent)

57. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

58. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '966 patent.

TWENTIETH AFFIRMATIVE DEFENSE
(Noninfringement of the '686 Patent)

59. BioNTech and Pfizer incorporate by reference paragraphs 1–111 of their Counterclaims as if fully set forth herein.

60. The manufacture, use, offer to sell, sale, and/or importation of Comirnaty® was not unauthorized and does not infringe any valid claim of the '686 patent.

* * *

WHEREFORE, BioNTech and Pfizer respectfully request the following relief:

a. an order dismissing each of CureVac's counterclaims with prejudice;

b. a judgment that BioNTech and Pfizer have not infringed any claim of any of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents;

c. a judgment that each asserted claim of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents is invalid;

d. a judgment that each of the '312, '278, '492, '920, '070, '910, '493, '525, '966, and '686 patents is unenforceable;

e. a declaration that this is an exceptional case and an award of attorney fees pursuant to 35 U.S.C. § 285;

f. an award of BioNTech's and Pfizer's costs and expenses in this action; and

g. such further and other relief as this Court may deem just and proper.

Dated: August 2, 2023

Respectfully submitted,

/s/Stephen E. Noona

Stephen E. Noona (VSB No. 25367)
KAUFMAN & CANOLES, P.C.
150 W. Main Street, Suite 2100
Norfolk, VA 23510-1665
Telephone: (757) 624-3239
Facsimile: (888) 360-9092
senoona@kaufcan.com

Counsel for Plaintiffs
BioNTech, SE, BioNTech Manufacturing GmbH, and Pfizer Inc.

Bruce M. Wexler *(pro hac vice)*
Eric W. Dittmann *(pro hac vice)*
Young J. Park *(pro hac vice)*
Mi Zhou *(pro hac vice to be filed)*
Max H. Yusem *(pro hac vice to be filed)*
Michael F. Werno *(pro hac vice to be filed)*
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
Telephone: (212) 318-6000
Facsimile: (212) 319-4090
brucewexler@paulhastings.com
ericdittmann@paulhastings.com
youngpark@paulhastings.com
mizhou@paulhastings.com
maxyusem@paulhastings.com
michaelwerno@paulhastings.com

Counsel for Plaintiffs
BioNTech SE and BioNTech Manufacturing GmbH

Dimitrios T. Drivas (*pro hac vice*)
John P. Scheibeler (*pro hac vice*)
Kevin J. Georgek (*pro hac vice*)
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020
Telephone: (212) 819-8200
Facsimile: (212) 354-8113
ddrivas@whitecase.com
jscheibeler@whitecase.com
kevin.georgek@whitecase.com

Sara Tonnies Horton *(pro hac vice)*
WILLKIE FARR & GALLAGHER LLP
300 North LaSalle Drive
Chicago, IL 60654
Telephone: (312) 728-9040
Facsimile: (312) 728-9199
shorton@willkie.com

Michael W. Johnson *(pro hac vice)*
Heather M. Schneider *(pro hac vice)*
Brian W. Frino *(pro hac vice to be filed)*
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019
Telephone: (212) 728-8000
Facsimile: (212) 728-8111
mjohnsonl@willkie.com
hschneider@willkie.com
bfrino@willkie.com

Counsel for Plaintiff
Pfizer Inc.